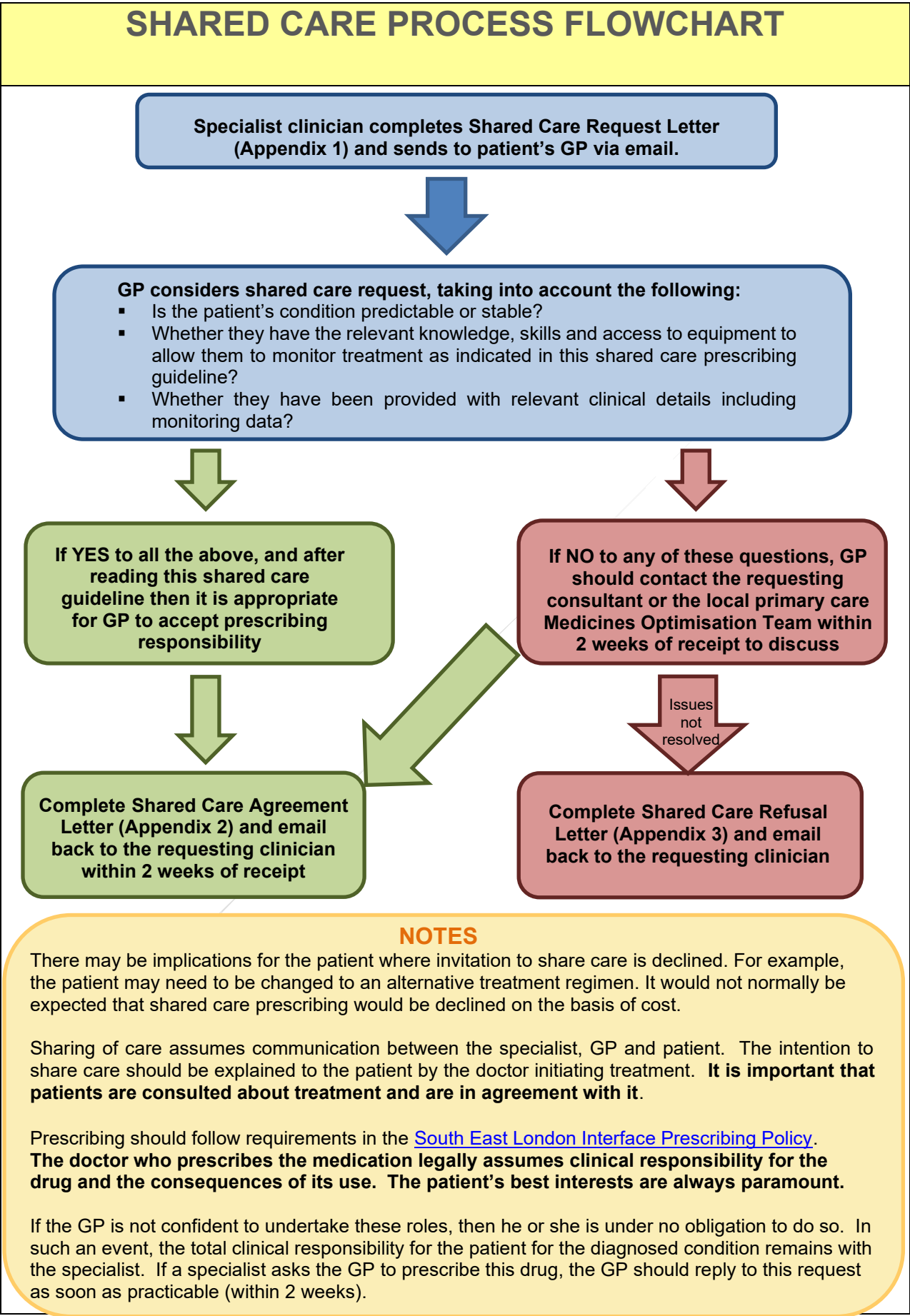




**SHARED CARE PRESCRIBING GUIDELINE**  
**for the prescribing and monitoring of stimulant therapy**  
**and anti-cataplectic agents in the management of**  
**Narcolepsy (+/- Cataplexy) and Idiopathic Hypersomnia in**  
**adults**

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### 1. AREAS OF RESPONSIBILITY

It is the responsibility of the specialist team to work with the Primary Care Lead to support GPs with drug monitoring, including consideration of patient recall systems where appropriate, and to advise on long-term stock issues where these become apparent.

| Consultant / Specialist team responsibilities                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>Ensure the stimulant therapy or anti-cataplectic agent is appropriately initiated e.g. no contraindications, cautions, interactions</li> <li>Ensure prescribing fits local or national agreement for use of the drug; off-label use of the drug should be discussed with the patient</li> <li>Counsel the patient on the risks and benefits of treatment, discuss potential adverse effects and any practical issues related to the use of stimulant therapy or anti-cataplectic agents</li> <li>Provide the patient with written information on the drug where available</li> <li>Provide the patient with information on self-management and advise them to contact secondary care specialist if they experience a deterioration of their disease management</li> <li>Undertake baseline investigations and initial monitoring according to local protocol</li> <li>Advise the patient to sign up to access their GP record online or via a mobile phone app where available; if this is not possible or suitable for the patient then ensure they are provided with a medicines monitoring record and advised of the importance of ongoing monitoring</li> <li>Advise the patient to be up to date with their routine vaccinations</li> <li>Signpost the patient to additional support services, such as charities and patient groups, where available and appropriate</li> <li>Report any suspected adverse effects to the MHRA: <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a></li> <li>Discuss shared care with patient and obtain patient agreement to request shared care</li> <li>Prescribe treatment for at least <b>the first 3 months</b> or until the patient is considered stable and shared care is agreed with GP; ongoing responsibility for prescribing stimulant therapy or anti-cataplectic agent will remain with the specialist team until this has been taken over by the GP</li> <li>If the GP does not agree to shared care continue to prescribe and monitor the stimulant therapy or anti-cataplectic agents</li> <li>When shared care is agreed:                             <ul style="list-style-type: none"> <li>Review patient at the request of GP should any problems arise (monitoring/ side-effects / lack of efficacy/ non-compliance)</li> <li>Arrange routine follow up (usually at least once per year)</li> <li>Communicate (<b>within 2 weeks</b>) with the GP if treatment is changed or stopped; if urgent communicate the change within 48 hours</li> <li>Confirm the patients monitoring schedule at each appointment.</li> </ul> </li> </ul> |

| General Practitioner responsibilities                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>To respond to shared care proposal <b>within 2 weeks</b> of receipt</li> <li>Provide ongoing prescriptions and adjust dose as advised by the specialist; annotate the prescription 'as per shared care guideline'</li> <li>Inform the patient of the monitoring arrangement required</li> <li>Encourage patient to register to access their record online and ensure this is updated; if the patient does not have online access enter blood results in patient held medicines monitoring record (for replacement or renewal of patient held medicines monitoring records contact the secondary care team)</li> <li>Undertake monitoring as outlined in the monitoring table</li> <li>To comment on the results of any monitoring undertaken in primary care to make the results and any impact of these clear to the patient</li> <li>Refer to the 'actions to be taken in primary care' page in the shared care guideline and follow the action specified</li> <li>Refer back to secondary care if the patient's condition deteriorates</li> <li>Stop treatment on the advice of secondary care or immediately if an urgent need to stop treatment arises</li> <li>Report any suspected adverse effects to the MHRA via the Yellow Card scheme: <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a></li> <li>Refer the patient back to secondary care if they are planning a family (males and females).</li> </ul> |

| Patient's / Carer's responsibilities                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| <ul style="list-style-type: none"> <li>Read pre-treatment information leaflets when provided by secondary care</li> <li>Attend scheduled appointments in primary and secondary care</li> <li>Contact the secondary or primary care team if unclear on any aspect of the treatment</li> <li>Report concerns about side effects to a healthcare professional</li> <li>Report any plans to start a family/ breastfeed to primary or secondary care</li> <li>Report any new or worsening symptoms to primary or secondary care</li> <li>Inform primary or secondary care or community pharmacist of any other medication being taken, including over the counter products or herbal remedies</li> <li>Take medicines as agreed and try to ensure no doses are missed</li> <li>Keep contact details up to date with both primary and secondary care</li> </ul> |

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- To arrange and attend all regular monitoring required and to confirm with the specialist or GP team that the results of these are satisfactory to continue the medication (contact can be via telephone to the admin team or patient having online access to their results in cases where confirmation is provided alongside the results that they are satisfactory).

2. CLINICAL INFORMATION

**NOTE:** The information here is not exhaustive. Please also consult the current Summary of Product Characteristics (SPC) for the stimulant therapy and anti-cataplectic agents listed below prior to prescribing for up to date prescribing information, including detailed information on adverse effects, drug interactions, cautions and contraindications (available via [www.medicines.org.uk](http://www.medicines.org.uk))

| Background                                                                                                                        | <p>Narcolepsy (+/- cataplexy) and idiopathic hypersomnia are both long-term and debilitating sleep conditions which are similar in their clinical presentation, differ in their diagnosis but may be managed in a parallel manner.</p> <p>Narcolepsy is a long-term condition that causes excessive sleepiness during the day and may also disrupt your sleep at night. You can also have sleep attacks where you fall asleep at inappropriate times during the day without any warning. The Epworth Sleepiness Scale is a questionnaire intended to measure daytime sleepiness. Narcolepsy is generally associated with an ESS of &gt;12, even after adequate night-time sleep.</p> <p>Cataplexy is a condition associated with narcolepsy that results in sudden muscle weakness triggered by strong emotions such as laughter, anger, fright or surprise. Muscle weakness can vary in severity and cataplexy attacks can differ in both nature and duration.</p> <p>Idiopathic Hypersomnia (IH) is a sleep disorder in which a person is excessively sleepy during the day and has great difficulty being awakened from sleep. Idiopathic means there is no clear cause. IH is similar to narcolepsy in that you are extremely sleepy but also different from narcolepsy because IH does not usually involve suddenly falling asleep (sleep attacks) or losing muscle control due to strong emotions (cataplexy). Furthermore, unlike narcolepsy, naps in idiopathic hypersomnia are usually not refreshing.</p> <p>The purpose of this document is to demonstrate the clinical use of stimulant and anti-cataplectic agents in the treatment of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adult patients. It is not within the scope of this document to provide guidance on diagnosis of this condition.</p> |                           |                        |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
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| Indications                                                                                                                       | <p>Note if indication is unlicensed or not</p> <p>The table below indicates the stimulant therapy and anti-cataplectic agents used in the treatment of narcolepsy (+/- cataplexy) and idiopathic hypersomnia in adult patients<br/>O = 'off-label' but considered routine treatment option<br/>X = unlicensed and not currently considered a routine option</p> <table><tr><th></th><th>Narcolepsy</th><th>Narcolepsy with Cataplexy</th><th>Idiopathic Hypersomnia</th></tr><tr><td><b>Stimulant agents</b></td><td></td><td></td><td></td></tr><tr><td>Modafinil</td><td>Licensed</td><td>Licensed</td><td>O</td></tr><tr><td>Methylphenidate XL</td><td>O</td><td>O</td><td>O</td></tr><tr><td>Methylphenidate IR</td><td>O</td><td>O</td><td>O</td></tr><tr><td>Dexamfetamine</td><td>Licensed</td><td>Licensed</td><td>O</td></tr><tr><td><b>Anti-cataplectic agents</b></td><td></td><td></td><td></td></tr><tr><td>Sodium oxybate</td><td>O</td><td>Licensed</td><td>X</td></tr><tr><td>Venlafaxine XL/IR</td><td>X</td><td>O</td><td>X</td></tr><tr><td>Clomipramine</td><td>X</td><td>Licensed</td><td>X</td></tr><tr><td>Fluoxetine</td><td>X</td><td>O</td><td>X</td></tr><tr><td colspan="4">The agent below is red listed and is NOT included in this shared care arrangement. Prescribing will remain with the sleep centre.</td></tr><tr><td>Pitolisant (NOT FOR SHARED CARE)</td><td>Licensed</td><td>Licensed</td><td>O</td></tr><tr><td>Solriamfetol (NOT FOR SHARED CARE)</td><td>Licensed</td><td>Licensed</td><td>X</td></tr></table>                                                                                                                                                                                                                                                                       |                           |                        |  | Narcolepsy | Narcolepsy with Cataplexy | Idiopathic Hypersomnia | <b>Stimulant agents</b> |  |  |  | Modafinil | Licensed | Licensed | O | Methylphenidate XL | O | O | O | Methylphenidate IR | O | O | O | Dexamfetamine | Licensed | Licensed | O | <b>Anti-cataplectic agents</b> |  |  |  | Sodium oxybate | O | Licensed | X | Venlafaxine XL/IR | X | O | X | Clomipramine | X | Licensed | X | Fluoxetine | X | O | X | The agent below is red listed and is NOT included in this shared care arrangement. Prescribing will remain with the sleep centre. |  |  |  | Pitolisant (NOT FOR SHARED CARE) | Licensed | Licensed | O | Solriamfetol (NOT FOR SHARED CARE) | Licensed | Licensed | X |
|                                                                                                                                   | Narcolepsy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Narcolepsy with Cataplexy | Idiopathic Hypersomnia |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| <b>Stimulant agents</b>                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                           |                        |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Modafinil                                                                                                                         | Licensed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Licensed                  | O                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Methylphenidate XL                                                                                                                | O                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | O                         | O                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Methylphenidate IR                                                                                                                | O                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | O                         | O                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Dexamfetamine                                                                                                                     | Licensed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Licensed                  | O                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| <b>Anti-cataplectic agents</b>                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                           |                        |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Sodium oxybate                                                                                                                    | O                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Licensed                  | X                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Venlafaxine XL/IR                                                                                                                 | X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | O                         | X                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Clomipramine                                                                                                                      | X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Licensed                  | X                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Fluoxetine                                                                                                                        | X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | O                         | X                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| The agent below is red listed and is NOT included in this shared care arrangement. Prescribing will remain with the sleep centre. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                           |                        |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Pitolisant (NOT FOR SHARED CARE)                                                                                                  | Licensed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Licensed                  | O                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |
| Solriamfetol (NOT FOR SHARED CARE)                                                                                                | Licensed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Licensed                  | X                      |  |            |                           |                        |                         |  |  |  |           |          |          |   |                    |   |   |   |                    |   |   |   |               |          |          |   |                                |  |  |  |                |   |          |   |                   |   |   |   |              |   |          |   |            |   |   |   |                                                                                                                                   |  |  |  |                                  |          |          |   |                                    |          |          |   |

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| <b>Place in Therapy</b><br>Indicate what drugs should have been tried before this drug is considered                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | See the following clinical pathways for further information: <ul style="list-style-type: none"> <li><a href="#">Pathway for the pharmacological management of excessive daytime sleepiness due to narcolepsy</a></li> <li><a href="#">Pathway for the pharmacological management of cataplexy associated with narcolepsy</a></li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                      |
| <b>Locally agreed off-label use</b><br>Including supporting information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | See the <a href="#">South East London Joint Medicines Formulary</a> for more information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                      |
| <b>Initiation and ongoing dose regime</b><br><b>Note:</b> <ul style="list-style-type: none"> <li>Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimized and with satisfactory investigation results for at least 12 weeks.</li> <li>The duration of treatment &amp; frequency of review will be determined by the specialist, based on clinical response and tolerability.</li> <li>All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.</li> <li>Termination of treatment will be the responsibility of the specialist.</li> </ul> | <b>Initial stabilisation:</b><br>(The loading period must be prescribed by the initiating specialist) <ul style="list-style-type: none"> <li>This will be for at least 3 months</li> </ul> <p>Some patients may take longer for their dose to stabilise, and in these cases, prescribing will remain with the initiating specialist until stabilized</p> <b>Maintenance dose (following initial stabilisation):</b> <ul style="list-style-type: none"> <li>After the initial stabilisation, GPs can be asked to continue prescribing treatment as per SE London shared care agreement (see appendix 1 below)</li> </ul> <b>Conditions requiring dose adjustment</b> <ul style="list-style-type: none"> <li>Sub-therapeutic</li> <li>Mild side-effects i.e. headache</li> <li>Some patients may have more individualised parameters set out by their secondary care specialist which fall outside the normal range; these should be communicated to primary care in writing.</li> </ul> <b>Duration of treatment</b> <ul style="list-style-type: none"> <li>Ongoing provided there is benefit, no reported intolerance and/or adverse effects.</li> </ul>                |                      |
| <b>Pharmaceutical aspects</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Route of administration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Oral                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Formulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | See appendix 4 below |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Administration details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | See appendix 4 below |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Other important information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | See appendix 4 below |
| <b>Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Baseline investigations:</b><br>Prior to initiation the following pre-treatment investigations will be undertaken in secondary care: <ul style="list-style-type: none"> <li>Height &amp; weight</li> <li>Blood pressure</li> <li>Heart rate</li> <li>Epworth Sleep Score</li> <li>Pregnancy test (if required)</li> <li>ECG (for initiation of modafinil, methylphenidate and dexamfetamine).</li> <li>Cataplexy severity (for initiation of venlafaxine, clomipramine, fluoxetine and sodium oxybate)</li> <li>Oximetry and mood (for initiation of sodium oxybate)</li> </ul> <p>In addition, the initiating secondary care specialist is responsible for:</p> <ul style="list-style-type: none"> <li>Documenting pre-treatment disease status as appropriate by indication</li> <li>Considering contraindications to treatment, co-morbidities or patient factors that would influence drug choice</li> <li>Counselling the patient on the risks and benefits of treatment including potential side effects, the need for ongoing monitoring and disease management</li> <li>To initiate, stabilise and supply treatment <b>for at least 3 months.</b></li> </ul> |                      |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>To inform patients of practical issues related to the use of stimulant +/- anti-cataplectic agents, such as administration, storage and maximum dose.</li> </ul> <p><b>Initial monitoring</b></p> <ul style="list-style-type: none"> <li>Monitoring at baseline and during initiation is the responsibility of the specialist, only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to the GP.</li> </ul> <p><b>Ongoing monitoring:</b></p> <ul style="list-style-type: none"> <li>See appendix 4 below</li> </ul> |                                                              |
| <b>Ongoing monitoring requirements to be undertaken by primary care</b>                                                                                                                                                                                                                                                | <b>Monitoring</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Frequency</b>                                             |
|                                                                                                                                                                                                                                                                                                                        | See appendix 4 below                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | See appendix 4 below                                         |
| <b>Adverse effects and management</b><br>Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme<br><a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a>                                                                                                         | <b>Result</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Action for GP</b>                                         |
|                                                                                                                                                                                                                                                                                                                        | See appendix 4 below                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Inform the named consultant of any reported adverse effects. |
| <b>Advice to patients and carers</b>                                                                                                                                                                                                                                                                                   | <p>The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.</p> <p><b>The patient should be advised to report any of the following signs or symptoms to their GP without delay:</b></p> <ul style="list-style-type: none"> <li>Rash develops.</li> <li>Onset of chest pain.</li> <li>Palpitations, breathlessness of unknown cause.</li> <li>Changes in mood, behaviour or thinking, suicidal thoughts.</li> </ul>                                                                                      |                                                              |
| <b>Criteria for stopping treatment</b><br>e.g. poor response, adverse effects requiring cessation                                                                                                                                                                                                                      | <p><b>Stopping criteria</b> (for all stimulant therapy and anti-cataplectic agents)</p> <p>Inform named consultant urgently. The sleep centre will advise appropriate weaning regimen.</p> <ul style="list-style-type: none"> <li>➤ Failure to respond to treatment or adverse effects necessitating withdrawal.</li> <li>➤ Pregnancy</li> <li>➤ Patient request</li> <li>➤ Rash develops, onset of chest pain, palpitations, breathlessness of unknown cause, and changes in mood, behaviour or thinking, suicidal thoughts.</li> </ul>                                                                                                                                         |                                                              |
| <b>Follow up arrangements</b><br>e.g. frequency of specialist clinic attendance                                                                                                                                                                                                                                        | <p>Request patient seen earlier if condition deterioration or adverse effects experienced between appointments</p> <p>It is the primary care prescriber’s responsibility to ensure patients adhere to the monitoring schedule. It should be clearly communicated to the patient how often they are required to attend.</p> <p>Concerns that the patient is unable to adhere to the monitoring schedule should be discussed with the secondary care team.</p> <p>Patients must be informed that they will be unable to continue the medication unless they adhere to the monitoring requirements.</p>                                                                             |                                                              |
| <b>Pregnancy, paternal exposure, and breast feeding</b><br>It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist. | <p><b>Pregnancy:</b></p> <ul style="list-style-type: none"> <li>See appendix 4 below</li> </ul> <p><b>Breastfeeding:</b></p> <ul style="list-style-type: none"> <li>See appendix 4 below</li> </ul> <p><b>For Specialist</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                              |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                          | Please complete the modafinil consent form (internal GSTT sleep centre consent form)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Additional information                                                                                                                                                                   | <p><b>Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.</b></p> <p>Some patients may have more individualised parameters set out by their secondary care specialist which fall outside the normal range; these should be communicated to primary care in writing.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <p><b>Evidence base for treatment and key references</b></p> <p>Include hyperlinks to original sources and access dates</p>                                                              | <ol style="list-style-type: none"> <li>Summary of Product Characteristics. Available online at: <a href="https://www.medicines.org.uk/emc#gref">https://www.medicines.org.uk/emc#gref</a></li> <li>British National Formulary. Available online at: <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>Department of Health. Green Book. Available online: <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book</a></li> <li>Department of Health. MHRA alert. Available online: <a href="https://www.gov.uk/drug-safety-update/modafinil-provigil-increased-risk-of-congenital-malformations-if-used-during-pregnancy">https://www.gov.uk/drug-safety-update/modafinil-provigil-increased-risk-of-congenital-malformations-if-used-during-pregnancy</a></li> </ol> |
| To be read in conjunction with the following documents                                                                                                                                   | <ul style="list-style-type: none"> <li><a href="#">South East London Joint Medicines Formulary Formulary</a></li> <li><a href="#">Pathway for the pharmacological management of excessive daytime sleepiness due to narcolepsy</a></li> <li><a href="#">Pathway for the pharmacological management of cataplexy associated with narcolepsy</a></li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>Local arrangements for referral</b></p> <p>Define the referral procedure from hospital to primary care prescriber &amp; route of return should the patient's condition change.</p> | <p>As per shared care process flow chart.</p> <p>Clinic letter/email request to GP for shared care consideration.</p> <p>Practice letter/email from GP to secondary care.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

### 3. COMMUNICATION AND SUPPORT

#### Guy's and St. Thomas' Hospital switchboard: 0207 188 7188

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Consultant/specialist team</b></p> <p><b>Rex Muza</b><br/>(Clinical Lead)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p><b>Tel:</b> 0207 188 3430<br/> <b>Email:</b> <a href="mailto:gst-tr.gsttsleepreferrals@nhs.net">gst-tr.gsttsleepreferrals@nhs.net</a></p>                                                                                                                                                                                                                                                                                                       |
| <p><b>Medication – Prescribing advice, interactions, availability of medicines</b></p> <p><b>Jasvinder Kaler Singh</b></p> <p><b>Medicines Information</b><br/>                     Guy's Hospital Medicines Information Department<br/>                     If you have any questions or concerns about these medicines, please call our helpline.</p> <p><b>Guy's Hospital Sleep Disorder Centre</b><br/>                     Open Mon-Fri 9am-5pm</p>                                                                                                                           | <p><b>Tel:</b> 0207 188 3430<br/> <b>Email:</b> <a href="mailto:gst-tr.thesleeppharmacistgstt@nhs.net">gst-tr.thesleeppharmacistgstt@nhs.net</a></p> <p><b>Tel:</b> 0207 188 3855/3853<br/> <b>Email:</b> <a href="mailto:gstt.medicinesinformation@nhs.net">gstt.medicinesinformation@nhs.net</a></p> <p><b>Tel:</b> 0207188 3430<br/> <b>Email:</b> <a href="mailto:gst-tr.gsttsleepreferrals@nhs.net">gst-tr.gsttsleepreferrals@nhs.net</a></p> |
| <p><b>Language and accessible support services</b><br/>                     If you need an interpreter or information about the pharmacological management of these conditions in a different language or format, please get in touch.</p> <p><b>NHS 111</b><br/>                     Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.</p> <p><b>NHS Choices</b><br/>                     Provides online information and guidance on all aspects of health and healthcare.</p> | <p><b>Tel:</b> 020 7188 8815<br/> <b>Email:</b> <a href="mailto:gstt.languagesupport@nhs.net">gstt.languagesupport@nhs.net</a></p> <p><b>Tel:</b> 111</p> <p><b>Website:</b> <a href="http://www.nhs.uk">www.nhs.uk</a></p>                                                                                                                                                                                                                        |

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Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear [insert Primary Care Prescriber's name]

Patient name: [insert patient's name]  
Date of birth: [insert date of birth]  
NHS Number: [insert NHS Number]  
Diagnosis: [insert diagnosis]

As per the agreed South East London shared care prescribing guideline for [insert medicine name] for the treatment of [insert indication], this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

| [Shared care can only be considered if the following requirements have been met. Please complete all parts of the right hand column to confirm this]     | Specialist to complete                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|
| The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:                                       | ..... weeks/months                                                        |
| Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory                                  | Yes <input type="checkbox"/>                                              |
| The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care                           | Yes <input type="checkbox"/>                                              |
| The risks and benefits of treatment have been explained to the patient                                                                                   | Yes <input type="checkbox"/>                                              |
| A contraceptive check for this patient has been completed within the last ..... months/week                                                              | Yes, Dated:..... <input type="checkbox"/><br>N/A <input type="checkbox"/> |
| The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed                             | Yes <input type="checkbox"/>                                              |
| The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments | Yes <input type="checkbox"/>                                              |
| I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)                   | Yes <input type="checkbox"/>                                              |
| I have included with the letter copies of the information the patient has received                                                                       | Yes <input type="checkbox"/>                                              |
| I have provided the patient with sufficient medication to last until                                                                                     | .....                                                                     |
| I have arranged a follow up with this patient in the following timeframe e.g. within 3 months / 6 months (please specify)                                | .....                                                                     |

Treatment was started on [insert date started] and the current dose is [insert dose and frequency].  
If you are in agreement, please undertake monitoring and treatment from [insert date] NB: date must be at least 1 month from initiation of treatment.  
The next blood monitoring is due on [insert date] and should be continued in line with the shared care guideline.  
Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

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Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear [insert Doctor's name]

Patient [insert Patient's name]

NHS Number [insert NHS Number]

Identifier [insert patient's date of birth and/or address]

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

| Primary Care Decision Form                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                             |                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------------------------------------|
| I agree/ do not agree (delete as appropriate) to participate in shared care for the following stimulant therapy or anti-cataplectic agent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                             |                                           |
| Stimulant therapy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                             |                                           |
| Modafinil<br><input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Methylphenidate<br><input type="checkbox"/> | Dexamfetamine<br><input type="checkbox"/> |
| Anti-cataplectic agents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                             |                                           |
| Venlafaxine XL<br><input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Venlafaxine IR<br><input type="checkbox"/>  | Clomipramine<br><input type="checkbox"/>  |
| Fluoxetine<br><input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Sodium oxybate<br><input type="checkbox"/>  |                                           |
| Where shared care is agreed, the primary care team agree to:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                             |                                           |
| <ul style="list-style-type: none"><li>Provide ongoing prescriptions; annotate the prescription 'as per shared care guideline'</li><li>Undertake ongoing monitoring as outlined in the shared care guideline</li><li>Inform the patient of the specific arrangements for organising and attending for blood tests (and any additional monitoring required)</li><li>Adjust the dose as advised by secondary care and undertake additional monitoring as outlined in the shared care guideline</li><li>Report any concerns e.g. adverse effects, inefficacy and non-compliance to secondary care for advice</li><li>Refer to abnormal blood test monitoring or adverse effect table in the shared care guideline and follow the action specified</li><li>Refer the patient back to secondary care if the patient's medical condition deteriorates</li><li>Refer the patient back to secondary care if they are planning a family (males and females) or report an unexpected pregnancy</li><li>Encourage the patient to sign up to access their GP online services/ via mobile app if available, if not available or if the patient does not wish to have online access then ensure that any changes in treatment and blood test results are documented in the patient's medicine monitoring record</li><li>Stop treatment on the advice of the secondary care or immediately if an urgent need arises</li></ul> |                                             |                                           |
| Where shared care is not agreed, please document reason(s) for declining to participate:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                             |                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                             |                                           |
| Completed by: Job Title:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Signature:                                  | Date:                                     |

I can confirm that I am willing to take on this responsibility from [insert date] and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: \_\_\_\_\_ Date: \_\_\_\_\_

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Primary Care Prescriber address/practice stamp:

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:  
Patient [insert Patient's name]

NHS Number [insert NHS Number]

Identifier [insert patient's date of birth and/or address]

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety, the local NHS in South East London have classified [insert medicine name] as a Shared Care medicine, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Tick which apply |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| 1. | <p><b>The prescriber does not feel clinically confident in managing this individual patient’s condition, and there is a sound clinical basis for refusing to accept shared care</b></p> <p>As the patients primary care prescriber I do not feel clinically confident to manage this patient’s condition because [insert reason]. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice.</p> <p><b>I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.</b></p> |                  |
| 2. | <p><b>The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement</b></p> <p>As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOG (Regional Medicines Optimisation Committees) or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time.</p> <p><b>Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you</b></p>                                                                                           |                  |
| 3. | <p><b>A minimum duration of supply by the initiating clinician</b></p> <p>As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p><b>Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.</b></p>                                                                                                                                                                    |                  |
| 4. | <p><b>Initiation and optimisation by the initiating specialist</b></p> <p>As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.</p> <p><b>Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.</b></p>                                                                                                                                                                                                                            |                  |

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|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| 5. | <b>Shared Care Protocol not received</b><br>As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed.<br>For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended.<br><i>Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.</i> |  |
| 6. | <b>Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted. NB: Capacity issues to be discussed with local primary care Medicines Optimisation Team prior to returning this form)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: \_\_\_\_\_ Date: \_\_\_\_\_

Primary Care Prescriber address/practice stamp:

Appendix 4 - Drug monitoring summary

| Modafinil – refer to pathway for place in therapy (see links on page 5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Modafinil promotes wakefulness by stimulating the brain to increase alertness and reduce excessive sleepiness during the day. Although there is no cure for narcolepsy, modafinil can help to control symptoms.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Ongoing monitoring to be undertaken by GP                                                                                                                                                                                                                                               | Stopping Criteria                                                                                                                                                                                                                                                                                                                               | Monitoring following dose changes                                                                                                                        | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p>Oral:<br/>modafinil 50-100mg/day gradually increasing over 4 to 6 weeks to maintenance dose of 400mg/day.</p> <p><b>Renal impairment</b><br/>GFR&lt;10<br/>Start at 50% normal dose and increase according to response.</p> <p><b>Hepatic impairment</b><br/>Reduce dose by half in patients with severe hepatic impairment.</p> <p><b>Older people</b><br/>Limited data available but potential for lower clearance and increased systemic exposure, it is recommended that patients ≥ 65 years of age commence therapy at 100 mg daily.</p> <p><b>Duration of Treatment</b><br/>Indefinitely if patient is responding well to treatment and in absence of significant side effects.</p> | <p><b>Baseline</b><br/>Blood pressure, heart rate, pregnancy test if necessary, Epworth Sleep Score.</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b><br/>Blood pressure, Epworth Sleep Score<br/>Ask patient about any rashes or change in mood and behaviour at each visit.<br/>Ask patient about side effects such as headache, chest pain.</p> <p>Hormonal contraceptives may be less effective when used with modafinil and therefore are not recommended. Modafinil consent form to be completed.</p> <p>Completion of modafinil consent form (internal GSTT sleep centre consent form)</p> <p>Please refer to this guidance for appropriate contraceptive methods: <a href="#">MHRA advice</a></p> | <p>Blood pressure, ECG and heart rate annually.<br/>Results of concern may be discussed with the Sleep Centre. <i>(Please see page 8 for contact details)</i></p> <p>Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.</p> | <p>Failure to respond to treatment or adverse effects necessitating withdrawal.</p> <p>Pregnancy</p> <p>Patient request</p> <p><b>STOP</b> modafinil if rash develops, onset of chest pain, palpitations, breathlessness of unknown cause, and changes in mood, behaviour or thinking, suicidal thoughts. Inform named consultant urgently.</p> | <p>GP to monitor blood pressure, heart rate.</p> <p>Inform the named consultant of <b>any reported</b> adverse effects i.e. rash, headache urgently.</p> | <p><b>Specialist:</b><br/>Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose, most recent blood pressure, Epworth Sleep Score and frequency of visits.</p> <p>Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic.</p> <p><b>GP</b><br/>Request patient seen earlier if condition deterioration or adverse effects experienced between appointments.</p> |

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| <b>Modafinil</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Practical issues including adverse effects, interactions, other relevant advice and information</b> (refer to BNF/SPC for full list):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <div><div><div>1.</div><div><b>Adverse Effects</b> - Patients should be advised to stop treatment if any sign of a rash occurs, any changes in mood, behaviour or thinking or you develop a fast heartbeat, chest pain or unexplained breathlessness. The side-effects mentioned above usually occur in the first 8 weeks of treatment and will be discussed by the doctor initiating the medication.</div></div><div><div>2.</div><div><b>Pregnancy and Breast Feeding</b> – Modafinil is not recommended for use in pregnancy or breastfeeding. Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.</div></div><div><div>3.</div><div><b>Effects on ability to drive or use machinery</b><br/>Modafinil can cause blurred vision or dizziness in some people therefore it may affect their ability to drive or use machines. Sleepiness associated with condition may also add to this.</div></div><div><div>4.</div><div><b>Abuse, misuse and diversion</b><br/>Patients should be carefully monitored for the risk of diversion, misuse and abuse of modafinil.</div></div></div> |
| <b>Clinically Significant Drug Interactions</b> (refer to BNF/SPC for full list) - <a href="https://www.medicines.org.uk/emc/product/4319/smpc">https://www.medicines.org.uk/emc/product/4319/smpc</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Modafinil is a weak enzyme inducer.</b><br><b>Hormonal contraceptives</b> , including oral contraceptive pills, implants, intrauterine contraceptive devices (IUCDs) and contraceptive patches may be less effective when used with modafinil and therefore are not recommended. Advise to use additional barrier methods.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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Methylphenidate (off-label use) - refer to pathway for place in therapy (see links on page 5)

Methylphenidate belongs to a group of medicines called stimulants. Methylphenidate works by stimulating the brain to increase alertness and reduce excessive sleepiness during the day. Although there is no cure for narcolepsy, methylphenidate can help to control symptoms.

| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Ongoing monitoring to be undertaken by GP                                                                                                                                     | Stopping Criteria                                                                                                                                                                                                                                                             | Monitoring following dose changes                                                                                                                                                                | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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| <p>Oral:</p> <p>Methylphenidate XL<br/>18-72mg every morning</p> <p>Methylphenidate IR<br/>10-60mg/day in divided doses.</p> <p><b>Renal or hepatic insufficiency</b><br/>There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency.</p> <p><b>Older people</b><br/>Methylphenidate should not be used in the elderly. Safety and efficacy has not been established in this age group.</p> <p><b>Duration of Treatment</b><br/>Indefinitely if patient is responding well to treatment and in absence of significant side effects<br/>If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.</p> | <p><b>Baseline</b><br/>Blood pressure, heart rate, ECG, Epworth Sleep Score<br/>Weight – to allow assessment of weight loss, pregnancy test if necessary</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b><br/>Blood pressure, pulse, weight, Epworth Sleep Score<br/>Ask patient about any changes to mood, behaviour or thinking.<br/>Ask patient about any chest pain, fast heartbeat or unexplained breathlessness<br/>Ask patient about any suicidal thoughts or thoughts about harming yourself.</p> | <p>Check weight, blood pressure and pulse annually.</p> <p>Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.</p> | <p>Failure to respond to treatment or adverse effects necessitating withdrawal.</p> <p>Pregnancy</p> <p>Patient request</p> <p><b>STOP</b> methylphenidate if changes in mood, behaviour or thinking or onset of suicidal thoughts.<br/>Inform named consultant urgently.</p> | <p>GP to monitor blood pressure, heart rate, weight.</p> <p>Inform the named consultant of <b>any reported</b> adverse effects such as chest pain, fast heartbeat and mood changes urgently.</p> | <p><b>Specialist:</b><br/>Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits.<br/>Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments.<br/>Advise GP to continue current plan until next reviewed in clinic.</p> <p><b>GP:</b><br/>Request patient seen earlier if condition deteriorates or adverse effects experienced between appointments.</p> |

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list):

1. Adverse effects
- Changes to mood, behaviour or thinking
  - Fast heartbeat, palpitations
  - Unexplained breathlessness
  - Weight loss
2. Pregnancy and Lactation
- Not recommended during pregnancy.

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- Breast-feeding is not recommended when using Methylphenidate
- Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

**3. Contra-indications:**

The list of contraindications is not exhaustive, please refer to the SPC for detail - <https://www.medicines.org.uk/emc/product/6872/smpc>

**4. Choice of formulation**

The choice of formulation of methylphenidate-containing product will be decided by the treating specialist on an individual basis and depends on the intended duration of effect. Generic prescribing permitted.  
SPS guidance on prescribing and switching between modified-release methylphenidate preparations can be accessed via this link - <https://www.sps.nhs.uk/articles/prescribing-and-switching-between-modified-release-methylphenidate/>

**5. Abuse, misuse and diversion**

- Patients should be carefully monitored for the risk of diversion, misuse and abuse of methylphenidate.

**Clinically Significant Drug Interactions** (refer to BNF/SPC for full list) - <https://www.medicines.org.uk/emc/product/6872/smpc>

- Coumarins:** Methylphenidate can possibly enhance the effect of coumarins

**Dexamfetamine - refer to pathway for place in therapy (see links on page 5)**

Dexamfetamine belongs to a group of medicines called stimulants. Dexamfetamine works by stimulating the brain to increase alertness and reduce excessive sleepiness during the day. Although there is no cure for narcolepsy, dexamfetamine can help to control symptoms.

| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                            | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                                                                                                                                      | Ongoing monitoring to be undertaken by GP                                                                                                                                          | Stopping Criteria                                                                                                                                                                                                   | Monitoring following dose changes                                                                                                                                                                | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <p><b>Oral:</b><br/>Dexamfetamine 10-60mg daily in divided doses.</p> <p><b>Renal or hepatic insufficiency</b><br/>There is no experience with the use of dexamfetamine in these patients. Peak plasma levels could be higher and elimination could be prolonged. Dexamfetamine should be used with special caution in this patient group by taking care of titration and dosage.</p> <p><b>Older people</b></p> | <p><b>Baseline</b><br/>Blood pressure, heart rate, ECG, Epworth Sleep Score</p> <p>Weight – to allow assessment of weight loss, pregnancy test if necessary</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b><br/>Blood pressure, pulse, weight, Epworth Sleep Score<br/>Ask patient about any changes to mood, behaviour or thinking.</p> | <p>Check weight, blood pressure and heart rate annually.</p> <p>Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.</p> | <p>Failure to respond to treatment or adverse effects necessitating withdrawal.</p> <p>Pregnancy</p> <p>Patient request</p> <p><b>STOP</b><br/>dexamfetamine if changes in mood, behaviour or thinking or onset</p> | <p>GP to monitor blood pressure, heart rate, weight.</p> <p>Inform the named consultant of <b>any reported</b> adverse effects such as chest pain, fast heartbeat and mood changes urgently.</p> | <p><b>Specialist:</b><br/>Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits. Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to</p> |

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| Dexamfetamine should not be used in the elderly. Safety and efficacy of dexamfetamine has not been established in this age group.<br><br><b>Duration of Treatment</b><br>Indefinitely if patient is responding well to treatment and in absence of significant side effects.<br>If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued. | Ask patient about any chest pain, fast heartbeat or unexplained breathlessness<br>Ask patient about any suicidal thoughts or thoughts about harming yourself. |  | of suicidal thoughts. Inform named consultant urgently. |  | continue current plan until next reviewed in clinic.<br><br><b>GP:</b><br>Request patient seen earlier if condition deteriorates or adverse effects experienced between appointments. |
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Dexamfetamine (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list):

1. Adverse effects

- Changes to mood, behaviour or thinking
- Fast heartbeat, palpitations
- Unexplained breathlessness
- Weight loss

2. Pregnancy and Lactation

- Not recommended during pregnancy.
- Breast-feeding is not recommended when using dexamfetamine

Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

3. Contra-indications:

The list of contraindications is not exhaustive, please refer to the SPC for detail.

<http://www.medicines.org.uk/emc/medicine/31119>

4. Abuse, misuse and diversion

- Patients should be carefully monitored for the risk of diversion, misuse and abuse of dexamfetamine.

**Clinically Significant Drug Interactions** (refer to BNF/SPC for full list) - <http://www.medicines.org.uk/emc/medicine/31119>

**MAO-A and MAO-B inhibitors: Risk of hypertensive crisis if given with dexamfetamine**

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Venlafaxine XL/IR (off-label use)- refer to pathway for place in therapy (see links on page 5)

Venlafaxine belongs to a group of medicines called anti-depressants. It can be used to treat cataplexy in narcolepsy. Venlafaxine is thought to work by interfering with certain chemicals in the brain which may be involved in causing the symptoms of cataplexy.

| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                           | Ongoing monitoring to be undertaken by GP      | Stopping Criteria                                                                                                                                                                                         | Monitoring following dose changes                                                                                                                                     | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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| <p><b>Oral:</b><br/>Venlafaxine XL 37.5-150mg in the morning.<br/>Venlafaxine IR 37.5-150mg daily (to confirm with sleep specialist if once or twice daily dosing required)</p> <p><b>Duration of Treatment</b><br/>Indefinitely if patient is responding well to treatment and in absence of significant side effects.</p> <p><b>Abrupt cessation:</b><br/>Abrupt cessation of antidepressants can result in status-cataplecticus (particularly cessation of venlafaxine). They should be withdrawn slowly and overlapped with next treatment option.</p> <p><b>Hepatic impairment</b><br/>50% dose reduction should be considered mild and moderate hepatic impairment. Risk versus benefit in patients with severe hepatic impairment.</p> <p><b>Renal impairment</b><br/>No change in dosage if caution is advised. Dose should be reduced by 50% in haemodialysis and in severe renal impairment (GFR &lt; 30 ml/min).</p> <p><b>Older people:</b><br/>No dose adjustment required. Caution should be exercised using lowest effective dose. Careful monitoring is required when an increase in the dose is required.</p> | <p><b>Baseline</b><br/>Blood pressure, heart rate, cataplexy severity, Epworth Sleep Score.</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b></p> <p>Blood pressure, heart rate, cataplectic episodes, Epworth Sleep Score.</p> | <p>Blood pressure and heart rate annually.</p> | <p>Failure to respond to treatment or adverse effects necessitating withdrawal.</p> <p>Patient request</p> <p>Inform named consultant urgently. Sleep centre will advise appropriate weaning regimen.</p> | <p>GP to monitor blood pressure and heart rate.</p> <p>Inform the named consultant of <b>any reported</b> adverse effects such as hypertension, anxiety urgently.</p> | <p><b>Specialist:</b><br/>Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits.</p> <p>Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic.</p> <p><b>GP:</b><br/>Request patient seen earlier if condition deterioration or adverse effects experienced between appointments.</p> |

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**Venlafaxine (cont)**

**Practical issues including adverse effects, interactions, other relevant advice and information** (refer to BNF/SPC for full list):

**1. Choice of formulation**

Modified release preparation should ONLY be prescribed for the management of cataplexy. Using the immediate release preparation may increase the risk of rebound cataplexy or the onset of status cataplecticus.

**2. Adverse effects**

- Abnormal dreams, insomnia,
- Anxiety; particularly on withdrawal
- Dizziness, drowsiness, confusion, nervousness
- Sweating, nausea & vomiting
- Hypertension, palpitations

**3. Effects on Ability to Drive and use Machines**

- Any psychoactive medicinal product may impair judgment, thinking, and motor skills. Therefore, any patient receiving venlafaxine should be cautioned about their ability to drive or operate hazardous machinery.

**4. Contraindications**

- Conditions associated with high risk of cardiac arrhythmia; uncontrolled hypertension

**5. Pregnancy and Lactation**

- Avoid unless potential benefit outweighs risk. Risk of withdrawal effects in neonate.
- Present in breast milk- avoid
- Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

**Clinically Significant Drug Interactions (refer to BNF/SPC for full list)**

The list of significant drug interactions is not exhaustive, please refer to the SPC for detail.

<https://www.medicines.org.uk/emc/product/2686/smpc>

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Clomipramine - refer to pathway for place in therapy (see links on page 5)

Clomipramine belongs to a group of medicines called anti-depressants. It can be used to treat cataplexy in narcolepsy. Clomipramine works by interfering with certain chemicals in the brain which may be involved in causing the symptoms of cataplexy.

| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                             | Ongoing monitoring to be undertaken by GP      | Stopping Criteria                                                                                                                                                                                                                                                      | Monitoring following dose changes                                                                                                                                                                    | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
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| <p><b>Oral:</b><br/>Clomipramine 10-75mg at night.</p> <p><b>Duration of Treatment</b><br/>Indefinitely if patient is responding well to treatment and in absence of significant side effects.</p> <p><b>Treatment cessation</b><br/>Withdrawal effects such as nausea, vomiting, abdominal pain, diarrhoea, insomnia, headache, nervousness and anxiety may occur within 5 days of stopping treatment. May be mild and self-limiting, can be severe. The risk of withdrawal symptoms is increased if treatment stopped suddenly after regular administration for ≥ 6 weeks. Reduce gradually over 4 weeks, or longer if withdrawal symptoms emerge<br/>Tricyclic and related antidepressants should be withdrawn slowly.</p> <p><b>Renal impairment</b><br/>Use with caution</p> <p><b>Hepatic impairment</b><br/>Sedative effects are increased in hepatic impairment. Avoid in severe liver disease.</p> <p><b>Older people</b><br/>May show a stronger response to clomipramine. Use with caution. Doses should be increased cautiously.</p> | <p><b>Baseline</b><br/>Blood pressure, heart rate, cataplexy severity, Epworth Sleep Score.</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b><br/><br/>Blood pressure, heart rate, cataplectic episodes, Epworth Sleep Score.</p> | <p>Blood pressure and heart rate annually.</p> | <p>Failure to respond to treatment or adverse effects such as hallucinations, disorientation, agitation or anxiety necessitating withdrawal.</p> <p>Patient request</p> <p>Inform named consultant urgently. Sleep centre will advise appropriate weaning regimen.</p> | <p>GP to monitor blood pressure and heart rate.</p> <p>Inform the named consultant of <b>any reported</b> adverse effects such as hallucinations, disorientation, agitation or anxiety urgently.</p> | <p><b>Specialist:</b><br/>Subject to response to treatment: 3 monthly, 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits.</p> <p>Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic.</p> <p><b>GP:</b><br/>Request patient seen earlier if condition deterioration or adverse effects experienced between appointments.</p> |

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**Clomipramine (cont)**

**Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list) :**

**1. Adverse effects**

- Abdominal pain, constipation (diarrhoea associated with withdrawal)
- Fatigue, impaired memory
- Aggression, restlessness
- Hypertension
- Flushing, muscle weakness/twitching

**2. Effects on Ability to Drive and use Machines**

- Drowsiness may affect the performance of skilled tasks (e.g. driving).

**3. Contraindications**

- Arrhythmias
- Acute porphyrias
- during the manic phase of bipolar disorder
- major depression
- heart block
- immediate recovery period after myocardial infarction

**4. Pregnancy and Lactation**

- Clomipramine is not recommended for use in women not using contraception
- Neonatal withdrawal symptoms reported if used during third trimester
- The quantity of clomipramine secreted into breast milk is small. Nursing mothers should be advised to withdraw from the medication or cease breast-feeding.
- Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

**5. Anticholinergic burden**

Elderly patients are particularly sensitive to anticholinergic, neurological, psychiatric, or cardiovascular effects. Their ability to metabolise and eliminate drugs may be reduced, leading to a risk of elevated plasma concentrations at therapeutic doses. Dose range in pathway is appropriate for older people (10-75mg daily)

**Clinically Significant Drug Interactions (refer to BNF/SPC for full list)**

The list of significant drug interactions is not exhaustive, please refer to the SPC for detail.

<https://www.medicines.org.uk/emc/product/2550>

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**Fluoxetine (off-label use)- refer to pathway for place in therapy (see links on page 5)**

**Fluoxetine** belongs to a group of medicines called anti-depressants. It can be used to treat cataplexy in narcolepsy. Fluoxetine works by interfering with certain chemicals in the brain which may be involved in causing the symptoms of cataplexy.

| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                                                                              | Ongoing monitoring to be undertaken by GP      | Stopping Criteria                                                                                                                                                                                         | Monitoring following dose changes                                                                                                                                                                                                                                                                                              | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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| <p><b>Oral:</b><br/>Fluoxetine 20-60mg daily in the morning.</p> <p><b>Hepatic impairment</b><br/>Reduce dose or increase dosing interval.</p> <p><b>Older people</b><br/>Caution is recommended when increasing the dose. Daily dose should generally not exceed 40 mg. Maximum recommended dose is 60 mg/day.</p> <p><b>Duration of Treatment</b><br/>Indefinitely if patient is responding well to treatment and in absence of significant side effects.<br/>If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.</p> | <p><b>Baseline</b><br/>Blood pressure, heart rate, cataplexy severity, Epworth Sleep Score.</p> <p>Weight – to allow assessment of weight loss</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b></p> <p>Blood pressure, heart rate, cataplectic episodes, Epworth Sleep Score.</p> | <p>Blood pressure and heart rate annually.</p> | <p>Failure to respond to treatment or adverse effects necessitating withdrawal.</p> <p>Patient request</p> <p>Inform named consultant urgently. Sleep centre will advise appropriate weaning regimen.</p> | <p>GP to monitor blood pressure and heart rate for patients on concomitant medications that may prolong QT or for those already under hypertension management.</p> <p>Inform the named consultant of <b>any reported</b> adverse effects such as palpitations, anxiety, urinary frequency/retention, weight loss urgently.</p> | <p><b>Specialist:</b><br/>Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits.</p> <p>Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic.</p> <p><b>GP:</b><br/>Request patient seen earlier if condition deterioration or adverse effects experienced between appointments.</p> |

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Fluoxetine (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list):

1. Adverse effects

- Abdominal pain, diarrhoea, constipation
- Nausea & vomiting, GI effects, dyspepsia
- Dizziness, drowsiness, visual disturbances, hallucinations
- Urinary retention, sexual dysfunction
- Bleeding disorders
- Anxiety, nervousness

2. Effects on Ability to Drive and use Machines

- May also impair performance of skilled tasks (e.g. driving, operating machinery)

3. Contraindications

The list of contraindications is not exhaustive, please refer to the SPC for detail- <https://www.medicines.org.uk/emc/product/15589/smpc>

4. Pregnancy and Lactation

Manufacturers advise to avoid during pregnancy unless the potential benefit outweighs the risk. There is a small increased risk of congenital heart defects when taken during early pregnancy. If used during the third trimester there is a risk of neonatal withdrawal symptoms, and persistent pulmonary hypertension in the newborn has been reported.

Present in breast milk- avoid

Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list)

The list of significant drug interactions is not exhaustive, please refer to the SPC for detail- <https://www.medicines.org.uk/emc/product/15589/smpc>

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Sodium Oxybate - refer to pathway for place in therapy (see links on page 5)

Sodium Oxybate is used to treat narcolepsy when cataplexy is also a problem. Sodium Oxybate promotes deep sleep and improves night-time sleep. It helps with excessive daytime sleepiness as well as helping the symptoms of cataplexy. It is sometimes used in combination with other medicines for narcolepsy. Although there is no cure for narcolepsy, sodium oxybate can help to control symptoms.

| Route, Dose, Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Monitoring Undertaken by Specialist before requesting shared care                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Ongoing monitoring to be undertaken by GP                                                                                                                                     | Stopping Criteria                                                                                                                                                                                                                                                                                                                        | Monitoring following dose changes                                                                                                                                                     | Follow Up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <p>Oral:</p> <p>The recommended starting dose is 4.5 g/day sodium oxybate (9 ml Xyrem®) divided into two equal doses of 2.25 g/dose (4.5 ml/dose).</p> <p>The dose should be titrated to effect based on efficacy and tolerability up to a maximum of 9 g/day divided into two equal doses of 4.5g/dose (9ml/dose) by adjusting up or down in dose increments of 1.5 g/day (i.e. 0.75 g/dose or 1.5 ml/dose). A minimum of two weeks is recommended between dosage increments.</p> <ul style="list-style-type: none"><li>Each dose of Xyrem® must be diluted with 60 ml of water in the dosing cup prior to ingestion. Single doses of 4.5g should not be given unless the patient has been titrated previously to that dose level.</li><li>Because food significantly reduces the bioavailability of sodium oxybate, patients should eat at least several (2-3) hours before taking the first dose of Xyrem® at bedtime. Patients should always observe the same timing of dosing in relation to meals. Xyrem® should be taken orally upon getting into bed and again between 2.5 to 4 hours later.</li></ul> <p>Patients advised to set an alarm and to remain in bed while they take their second dose.</p> <p><b>Discontinuation of Xyrem®:</b> The discontinuation effects of sodium oxybate have not been systematically evaluated in controlled clinical trials. If the patient stops medication for more than 14 consecutive days, titration should be restarted as per initiation regimen.</p> | <p><b>Baseline</b></p> <p>Blood pressure, heart rate, Epworth Sleep Score, pregnancy test if necessary, weight – to allow assessment of weight loss, severity of cataplectic episodes. oximetry (only avoid in severe OSA) mood</p> <p><b>Ongoing at 6 and 12 monthly clinic appointments</b></p> <p>Blood pressure, heart rate, Epworth Sleep Score, pregnancy test if necessary, weight – to allow assessment of weight loss. Cataplexy episodes. Ask the patient about any changes in mood, behaviour or side effects such as nocturnal enuresis, sleep walking. Any change in breathing i.e increased snoring, reports of apnoea.</p> | <p>Check weight, blood pressure and pulse annually.</p> <p>Adverse reactions and inform the named consultant if concerns that the patient may be misusing the medication.</p> | <p>Failure to respond to treatment or adverse effects necessitating withdrawal.</p> <p>Pregnancy</p> <p>Patient request</p> <p><b>STOP</b> sodium oxybate if changes in mood, behaviour or thinking or onset of suicidal thoughts. Inform named consultant urgently.</p> <p>Sleep centre will advise an appropriate weaning regimen.</p> | <p>Check weight, blood pressure and pulse annually.</p> <p>Inform the named consultant <b>of any reported</b> adverse effects such as sleep walking, nocturnal enuresis urgently.</p> | <p><b>Specialist:</b></p> <p>Subject to response to treatment: 6 monthly or 12 monthly if well controlled and stable.</p> <p>Send a letter/results notification to the GP after each clinic attendance indicating current dose and Epworth sleep score and frequency of visits.</p> <p>Advise GP on review, duration and or discontinuation of treatment when necessary. Inform GP of patients who do not attend clinic appointments. Advise GP to continue current plan until next reviewed in clinic.</p> <p><b>GP:</b></p> <p>Request patient seen earlier if condition deterioration or adverse effects experienced between appointments.</p> |

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| <p><b>Patients with hepatic impairment:</b><br/>The starting dose should be halved in patients with hepatic impairment, and response to dose increments monitored closely.</p> <p><b>Patients with renal impairment:</b> Patients with impaired renal function should consider a dietary recommendation to reduce sodium intake.</p> <p><b>Elderly patients:</b> Elderly patients should be monitored closely for impaired motor and/or cognitive function when taking sodium oxybate.</p> <p><b>Duration of Treatment:</b><br/>Indefinitely if patient is responding well to treatment and in absence of significant side effects.</p> |  |  |  |  |  |
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Sodium Oxybate (cont)

Practical issues including adverse effects, interactions, other relevant advice and information (refer to BNF/SPC for full list):

- 1. Storage**  
Sodium oxybate comes in a bottle with two containers for mixing the medication. Both the bottle and storage containers have child proofed caps. The mixed solution should be kept in a bed side drawer just before going to sleep. If there are children in the house, this draw should be locked or be out of the reach of children. Discard diluted solution after 24 hours.
- 2. Adverse effects**
- Sleep walking
  - Urinary incontinence
  - Drowsiness, dizziness, blurred vision
  - Nausea, vomiting, weight loss, abdominal pain
  - Hypertension, palpitations
- 3. Effects on Ability to Drive and use Machines**
- Sodium oxybate has a major effect on the ability to drive and use machines. These patients should already be known to the DVLA
  - For at least 6 hours after taking sodium oxybate, patients must not undertake activities requiring complete mental alertness or motor coordination, such as operating machinery or driving.
  - When patients first start taking sodium oxybate, they should take extreme care when driving, operating heavy machines or performing any other task which is dangerous or requires full mental alertness.
- 4. Contraindications**  
The list of contraindications is not exhaustive, please refer to the SPC for detail.  
<https://www.medicines.org.uk/emc/product/178>

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5. Pregnancy and Lactation

- Not recommended during pregnancy.
- Breast-feeding is not recommended when using Sodium oxybate.

Any patient considering becoming pregnant or has discovered they are pregnant should be referred back to their consultant immediately and shared care will no longer apply for the duration of the pregnancy and while breast feeding.

Clinically Significant Drug Interactions (refer to BNF/SPC for full list) - <https://www.medicines.org.uk/emc/product/178>

- **Alcohol:** The combined use of alcohol with sodium oxybate may result in potentiation of the central nervous system-depressant effects of sodium oxybate.
- **Sedative hypnotics or other CNS depressants:** Sodium oxybate should not be used in combination
- Since sodium oxybate is metabolised by GHB dehydrogenase there is a potential risk of an interaction with drugs that stimulate or inhibit this enzyme (e.g. valproate, phenytoin or ethosuximide). No interaction studies have been conducted in human subjects, although if sodium oxybate and valproate are used concomitantly, a decrease in sodium oxybate dose by 20% is recommended.
- Possible additive effect of antidepressants and sodium oxybate cannot be excluded. The rates of adverse events are increased when sodium oxybate is co-administered with tricyclic antidepressants.
- There is a higher risk of sleep apnoea in patients with BMI ≥ 40kg/m2.