

## Pancreatic Enzyme Replacement Therapy (PERT) shortages briefing document

### Introduction

The [National Patient Safety Alert \(NatPSA\)](#)<sup>1</sup>, Shortage of Pancreatic enzyme replacement therapy (PERT) (May 2024), addressed the ongoing shortage of Creon®, Nutrizym® and Pancrex®. PERT is indicated for the treatment of pancreatic exocrine insufficiency (PEI) such as in cystic fibrosis (CF), pancreatic cancer, and pancreatitis<sup>1</sup>. A further [National Patient Safety Alert \(NatPSA\)](#)<sup>2</sup> was issued on 18th December 2024, which sets out additional actions for clinicians and pharmacists regarding PERT.

Currently the following **licensed** preparations are affected<sup>3</sup>:

- **Creon® 10,000 and 25,000 capsules:** Limited supply until 2 January 2026; Creon 10,000 only supplied to hospitals, prioritised for children and those unable to swallow larger capsules.
- **Nutrizym® 22 capsules:** Intermittently available but are unable to fully support a significant uplift in demand, prioritised for those unable to tolerate Creon® preparations.
- **Pancrex V® 125mg and 340mg capsules:** Expected to be out of stock until 3 January and June 2025
- **Pancrex V® oral powder:** Expected to be out of stock until 2 May 2025.

### Advice for healthcare professionals:

- Table 1 summarises key recommendations for clinicians and pharmacists to ensure the appropriate management of PERT shortages in primary and secondary care.
- All healthcare professionals should consult [Specialist Pharmacy Service Prescribing and ordering available pancreatic enzyme replacement therapies](#)<sup>3</sup> [Medicines Supply Tool](#) for the latest updates.
- For further assistance healthcare professionals can contact [Medicines Advice](#) across England via 03007708564 or [asksp.nhs@sps.direct](mailto:asksp.nhs@sps.direct) Monday to Friday, 9am to 5pm.

**Table 1: Summary of key recommendations in primary and secondary care**

<p style="writing-mode: vertical-rl; transform: rotate(180deg);">London alternative supply route for unlicensed medicines<sup>1,2,3</sup></p>	<p>South East London ICB in collaboration with our local hospitals and community pharmacies have a process in place to help patients continue to have access to Creon® during the ongoing PERT shortage. This arrangement enables community pharmacies to obtain the unlicensed import, Pangrol® (unlicensed imported Creon®), from <a href="#">OXFORD PHARMACY STORES (OPS)</a> during periods of limited availability.</p> <p>Clinicians and community pharmacies are reminded to:</p> <p><b>1. Source licensed PERT:</b></p> <ul style="list-style-type: none"> <li>• Continue to source licensed PERT through your usual wholesalers, as per <a href="#">NatPSA</a> and follow <a href="#">SSP060 and SSP061</a> guidance (applicable to Creon® only).</li> <li>• Refer to <a href="#">SPS</a><sup>3</sup> for latest updates on stock availability and information on available preparations.</li> <li>• For information on supplies, pharmacists and patients can contact: <ul style="list-style-type: none"> <li>○ Creon® Helpline operated by Viatris UK: via 0800 8086410 Monday to Friday from 9:00 to 17:00 for information on Creon® supplies or contact customer services on 01707 853100 or via <a href="mailto:productenquiries@viatris.co.uk">productenquiries@viatris.co.uk</a></li> <li>○ Nutrizym®: contact Zentiva on 08000 902408 or email <a href="mailto:ukcustomerservices@zentiva.com">ukcustomerservices@zentiva.com</a>.</li> </ul> </li> </ul> <p><b>2. Unlicensed Imported products:</b></p> <ul style="list-style-type: none"> <li>• Prescribe unlicensed imports of PERT only when licensed alternatives are unavailable.</li> <li>• Access unlicensed import via usual wholesalers or OPS.</li> <li>• Please secure the most cost effective supply of unlicensed PERT (which may be through your usual wholesaler).</li> <li>• London ICBs have established provisions for community pharmacies to source unlicensed imported Pangrol® from a supplier OPS.</li> </ul> <ul style="list-style-type: none"> <li>• Agreements are in place for bulk purchases of this stock, allowing for a shorter lead time of 1 to 2 days for delivery, with the cost included in the products price.</li> </ul>
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- Use OPS only when licensed stock of Creon® unavailable from a wholesaler and the patient has 14 days or less of their medicine.
- On receipt of a prescription, pharmacies should register with OPS to set up an account via [register for a new account](#) or return the completed [OPS New Customer Verification Form](#).
- Refer to [Managing PERT Shortages: Imported Creon® alternative Pangrol®](#) for further information on prescribing and ordering from OPS.

## Clinicians

- Review patients with indications other than CF in accordance with the [NatPSA<sup>1</sup>](#) and the [Pancreatic Society of Great Britain and Ireland position statement on the PERT shortage<sup>4</sup>](#) which provides prescribing advice on management of **adults** with pancreatic exocrine insufficiency (PEI).
- For neonates and children, refer to the **Neonatal & Paediatric Pharmacy Group's** [position statement<sup>5</sup>](#)
- **Specialist advice should be sought for the following patient groups:**
  - Paediatric patients with PEI.
  - Adult and paediatric patients with cystic fibrosis (CF).  
Trusts have confirmed that they have contacted all their adult and paediatric CF patients and provided advice on managing the PERT shortage<sup>6</sup>.
  - Patients with small bowel neuroendocrine tumours (NETs) may be at risk of carcinoid syndrome, mesenteric fibrosis, short bowel syndrome.
  - Those patients for whom the advice in the [NatPSA<sup>1</sup>](#) is unsuitable.
- General practice clinicians who need further advice on managing non-CF patients without a formal referral should utilise the Advice and Guidance (A&G) service for support.
- Prescribe licensed PERT first. If unavailable, prescribe unlicensed imports as alternative, in line with [General Medical Council guidance \(GMC\): Prescribing unlicensed medicines](#).
- The enzyme composition of unlicensed imports may differ from UK licensed products<sup>1,2</sup>. Refer to the corresponding [Summary of Product Characteristics](#) or datasheets for specific product information.
- Refer to [Find PERT alternatives and equivalences<sup>3</sup>](#) tool to identify options matching a patient's current therapy with equivalent UK licensed products.
- Advise patients to request a repeat prescription shortly after their previous one is dispensed, advising at least **two** weeks in advance to ensure supply.
- Prescribe PERT on a separate prescription, allowing for dispensing at another pharmacy if necessary, without disrupting the supply of patients' other medication.
- Prescribe ONE months' supply.
- A prescription for [a supply of unlicensed PERT preparation](#) must be written accurately;
  - Prescriber must state; '*Specified PERT product ('Imported' or 'Special order')*' included as part of the drug **name field on an electronic or paper FP10**, for example: Creon® 10000 gastro-resistant capsules (Imported).
  - If the unlicensed PERT products are not visible on GP prescribing systems to select, an FP10 paper prescription should be issued as '*Specified PERT product (Special Order)*' or '*Specified PERT product (Imported)*'<sup>7</sup>.
  - Prescribers are advised to amend the prescription to ensure it is written correctly for the unlicensed medicine sourced.
- Unlicensed products can be sourced via community pharmacies through their usual wholesalers or Oxford pharmacy stores (OPS) but availability and lead times may vary.
- When prescribing Pangrol®, the prescriber must clearly state on a FP10 paper prescription:
  - Pangrol® capsules 10,000/ 25,000\* (delete as appropriate) (**Imported**)
  - Special Order
  - Dosage for patient
  - Quantity (note Pangrol® comes in 200 capsule packs)

### Patient Counselling:

- Refer to [Information for Patients](#): Pancreatic enzyme replacement therapy (PERT).
- There is clinical difference between Pangrol® and Creon®. Clinicians should counsel patients on the following:

- The Pangrol® patient information leaflet (PIL) states: "If you have difficulty swallowing the capsule whole, you can also carefully open it over a suitable container by pulling it apart and swallowing only the contents with a little liquid immediately and without chewing"<sup>8</sup>.
  - The Creon® PIL states: If the capsules cannot be taken whole, "open the capsules and mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt). Swallow the mixture straight away, without chewing"<sup>9</sup>.
- Adhere to the requirements laid out in the [NatPSA<sup>1</sup>](#) alert.
  - Pharmacists presented with repeat prescription for PERT should dispense **one month's supply** in accordance with Serious Shortage Protocol [SSP060 and SSP061<sup>10,11</sup>](#).
  - Continue to **source licensed PERT** through your usual wholesalers' stock which is usually released from manufacturers to wholesalers three times a month.
  - Engage with wholesalers to understand the supply chain and estimated time for stock availability for licensed and unlicensed PERT.
  - Pharmacists and patients can also contact:
    - Creon® Helpline operated by Viatris UK via 0800 8086410 or customer services on 01707 853 100 or [productenquiries@viatris.com](mailto:productenquiries@viatris.com) regarding Creon® supplies<sup>12</sup>.
    - Nutrizym®: contact Zentiva on 08448 793188 (for pharmacists) and 08000 902408 (for patients) or email [ukcustomerservices@zentiva.com](mailto:ukcustomerservices@zentiva.com).
  - Consider unlicensed imports of PERT only where licensed alternatives are unavailable, working with prescribers to ensure orders are placed within appropriate time frames<sup>1,2</sup>. For further information refer to [SPS<sup>3</sup>](#).
  - Please secure the most cost-effective supply of unlicensed PERT (which may be through your usual wholesaler or OPS).
  - Ensure prescriptions for [supply of unlicensed preparations<sup>13</sup>](#) are written correctly with '(Imported)' included as part of the drug name field e.g. Creon® 10000 gastro-resistant capsules (Imported).
  - Liaise with the prescriber and refer the prescription back to them to ensure it is written correctly<sup>9</sup>.
  - If patient is due to run out in the next 14 days and there is no UK Creon® available, consider ordering Pangrol® from OXFORD PHARMACY STORES and get a new prescription to ensure full costs are covered.
  - **Pangrol®** is an alternative unlicensed brand, which has direct equivalent strengths as Creon®.
  - Provide the relevant patient information leaflet (PIL) when dispensing Pangrol®:
    - [Pangrol® 10,000](#)
    - [Pangrol® 25,000](#)
  - There is a clinical difference between Pangrol® and Creon®. Pharmacist should counsel patients on how to take Pangrol®.
    - The Pangrol® PIL states: "If you have difficulty swallowing the capsule whole, you can also carefully open it over a suitable container by pulling it apart and swallowing only the contents with a little liquid immediately and without chewing"<sup>8</sup>.
    - The Creon® PIL states: If the capsules cannot be taken whole, "open the capsules and mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt). Swallow the mixture straight away, without chewing"<sup>9</sup>.
  - Ensure correct endorsements are made in accordance with the [prescription endorsement requirements for non-Drug Tariff specials<sup>14</sup>](#).
    - Endorse paper FP10 prescription as per SSP: where SSP endorsement functionality is available on the dispensing system, select SSP and input the three-digit reference number and select in the system the SSP item that has been supplied<sup>10,11</sup>.
    - Example, SSP 06: pharmacy contractor **selects in system or endorses** - Creon® 25000 gastro resistant capsules x REDUCED QUANTITY IN LINE WITH SSP.
  - Ensure Pangrol® scripts are endorsed with the following information:
    - **Amount dispensed over pack size** (e.g. 50/200).
    - **Invoice price per pack size** from which the order was supplied less any discount or rebate, include delivery cost where applicable

- Manufacturers'/importers' (Target Healthcare) MHRA license number which is MS43086/WDA(H)43086
- Batch number of the product supplied
- The letters 'SP' to indicate it is a special and for costs incurred in obtaining the item.
- Refer to [Managing PERT Shortages: Imported Creon® alternative Pangrol®](#) for further information on prescribing and ordering.

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