

## Trurapi® ▼ (insulin aspart) for Adults – Fact Sheet for Prescribers

### What is Trurapi®?

Trurapi® (insulin aspart) is a biosimilar of NovoRapid® (insulin aspart) and is a rapid acting insulin analogue.

It has been demonstrated to be highly similar to NovoRapid®, the originator medicine, with no clinically meaningful differences in quality, safety, or efficacy and is considered therapeutically equivalent within its licensed indications.

### SE London Adult Formulary Position

Trurapi® is the preferred first-line insulin aspart product for adults (aged 18 years and over) when initiating insulin aspart treatment, due to lower acquisition cost.

- Trurapi® pre-filled pens and cartridges are approximately 30% cheaper than the NovoRapid® equivalent devices.
- Trurapi® vials are approximately 15% cheaper than NovoRapid® vials.

Clinicians titrating a patient's NovoRapid® dose due to inadequate glycaemic control should consider changing to Trurapi® while maintaining consideration of user ability and satisfaction with a device.

Patients whose clinical condition remains stable on NovoRapid® should continue on their current treatment.

Routine blanket switching between different insulin aspart preparations is **not** supported.

Trurapi® is an AMBER 1 medication, which means it is suitable for initiation in primary care, following specialist recommendation. A suitably trained diabetes specialist may include a consultant, GP with extended roles (GPwER) or appropriately trained diabetes specialist practitioner (GP, nurse or non-medical prescriber).

### Prescribing Trurapi®

Insulin aspart should always be prescribed by **brand name**, to ensure that substitution of a biosimilar product does not occur when the medicine is dispensed.


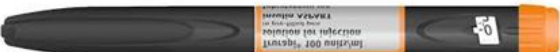





When switching from NovoRapid® to Trurapi®:

- A unit – for-unit dose conversion is recommended, adjusted for any existing hypo- or hyperglycaemia.
- Prescribe compatible needles which meet the universal ISO 11608-2 standard.
- Ensure appropriate support and close monitoring to assess changes in glycaemic control are in place e.g. glucose monitoring.
- Ensure the patient is aware of the change and can use the new insulin device and that prescribing records have been updated.

### Additional Information:

- Trurapi® is licensed for the treatment of diabetes in children aged 1 years and above, however has not been approved for use on the SE London paediatric formulary for children and young people (under the age of 18 years old).
- NovoRapid® remains available for adults where using or switching to a biosimilar is not clinically appropriate (e.g. where the patient's insulin pump is not licensed for use with the biosimilar insulin, the patient requires use of a "smart" re-usable insulin delivery device (NovoPen® 6 / NovoPen® Echo Plus) to allow data sharing with a healthcare professional).

## Key differences between NovoRapid® and Trurapi® available devices

Originator medicine - NovoRapid®	Biosimilar medicine- Trurapi® ▼
<p><b>NovoRapid® Flexpen® 100 units/ml pre-filled pen device (3ml)</b></p>  <ul style="list-style-type: none"> <li>• Can dial up 1-60 units</li> </ul>	<p><b>Trurapi® Solostar® 100 units/ml pre-filled pen device (3ml)</b></p>  <ul style="list-style-type: none"> <li>• Can dial up 1-80 units</li> </ul>
<p><b>NovoRapid® Penfill® 100 units/ml cartridges (3ml)</b></p>  <ul style="list-style-type: none"> <li>• Compatible reusable pen devices: <ul style="list-style-type: none"> <li>▪ NovoPen®6 (can dial up 1-60 units)</li> <li>▪ NovoPen Echo® (can dial up 0.5-30 units)</li> </ul> </li> <li>Both are smartpen devices</li> </ul>	<p><b>Trurapi® Cartridge 100 units/ml cartridges (3ml)</b></p>  <ul style="list-style-type: none"> <li>• Compatible pen devices: <ul style="list-style-type: none"> <li>▪ Allstar®Pro Pen (can dial up 1-80 units)</li> <li>▪ JuniorSTAR®pen (can dial up 0.5-30 units)</li> </ul> </li> <li>Both are NOT smartpen devices</li> </ul>
<p><b>NovoRapid® vial 100 units/ml vial (10ml)</b></p>  <ul style="list-style-type: none"> <li>• Insulin pump compatibility: Compatible with the majority of insulin pumps.</li> </ul>	<p><b>Trurapi® vial 100 units/ml vial (10ml)</b></p>  <ul style="list-style-type: none"> <li>• Insulin pump compatibility: Limited. Check insulin pump manufacturer product literature to confirm compatibility prior to initiating.</li> </ul>
<p><b>NovoRapid® PumpCart® 100 units/ml solution for injection 1.6ml cartridges</b></p> 	<p>Trurapi® is <b>not available</b> as Pumpcart® device</p>

### Useful Resources:

- TruRapi Patient support materials are available (in multiple languages) at: <https://www.mysanofiinsulin.co.uk/trurapi/>
- Summary of product characteristics can be found at [www.medicines.org.uk](http://www.medicines.org.uk)

## References:

1. Biosimilar medicines: <https://www.england.nhs.uk/medicines-2/biosimilar-medicines/>
2. Kapitza C, et al. Single-Dose Euglycemic Clamp Study Demonstrating Pharmacokinetic and Pharmacodynamic Similarity Between SAR341402 Insulin Aspart and US- and EU-Approved Versions of Insulin Aspart in Subjects with Type 1 Diabetes. *Diabetes Technology & Therapeutics* Vol. 22, No. 4 Published Online: 24 March 2020: <https://doi.org/10.1089/dia.2019.0351>
3. Committee for Medicinal Products for Human Use (CHMP) Assessment report: Insulin aspart Sanofi, EMA/CHMP/269410/2020: 30 April 2020: [https://www.ema.europa.eu/en/documents/assessment-report/insulin-aspart-sanofi-epar-public-assessment-report\\_en.pdf](https://www.ema.europa.eu/en/documents/assessment-report/insulin-aspart-sanofi-epar-public-assessment-report_en.pdf)
4. Garg SK, et al. Efficacy and Safety of Insulin Aspart Biosimilar SAR341402 Versus Originator Insulin Aspart in People with Diabetes Treated for 26 Weeks with Multiple Daily Injections in Combination with Insulin Glargine: A Randomized Open-Label Trial (GEMELLI 1) *Diabetes Technology & Therapeutics* Vol. 22, No. 2 Published Online: 22 January 2020: <https://doi.org/10.1089/dia.2019.0382>
5. Garg SK, et al. Safety, Immunogenicity, and Glycemic Control of Insulin Aspart Biosimilar SAR341402 Versus Originator Insulin Aspart in People with Diabetes Also Using Insulin Glargine: 12-Month Results from the GEMELLI 1 Trial. *Diabetes Technology & Therapeutics* Vol. 22, No. 7: Published Online: 30 June 2020: <https://doi.org/10.1089/dia.2020.0008>
6. Novo Nordisk Ltd. NovoRapid FlexPen, summary of product characteristics. *Electronic Medicines Compendium*. Last revised 1 January 2021: <https://www.medicines.org.uk/emc/product/7920/smpc#gref>