

TRURAPI® (biosimilar insulin aspart)

The Cheshire and Merseyside Area Prescribing Group recommends Trurapi® (biosimilar insulin aspart) as the preferred first-line choice when prescribing insulin aspart

POSITION STATEMENT

The Cheshire and Merseyside Area Prescribing Group recommends Trurapi® as the preferred first-line choice when prescribing insulin aspart and that:

- **All new patients requiring insulin aspart should be initiated on Trurapi® provided this is appropriate for the individual patient.**
- **Opportunistic and managed switches from NovoRapid® to Trurapi® should be undertaken in primary and secondary care, unless there is a clinical reason that an individual patient should not be switched.**

Background

Biosimilars are considered therapeutically equivalent and interchangeable with their reference product^{1,2,3} and it is likely that their availability and use will become more widespread over the next few years. Biosimilars have the potential to offer the NHS considerable cost savings, especially as they are often used to treat long term conditions.

Trurapi® (biosimilar insulin aspart) demonstrates similar pharmacokinetics, has been shown to be non-inferior in terms of glycaemic control, and has a similar safety and immunogenicity profile to the reference product (NovoRapid®), in both type 1 and type 2 diabetes^{4,5}.

There is no scientific rationale to expect different clinical outcomes when switching between biosimilars of the same reference product and this is supported by real-world data⁵. Patients have been safely switched from NovoRapid® to Trurapi® in many areas across England.

Rationale

The NHS list price of Trurapi® pre-filled pens and cartridges is approximately 30% less, and the vials approximately 15% less than NovoRapid®. Based on current expenditure across NHS Cheshire and Merseyside, switching 80% of patients from NovoRapid® to Trurapi® would save approximately £1 million per annum. The use of best value biological medicines is one of 16 national medicines optimisation priorities identified by NHS England⁶.

Costs

Insulin Aspart 100units/ml solution for injection	Pack Size	NHS price ⁷ (June 2024)
NovoRapid® 100units/ml 3ml cartridges	5 x 3ml cartridges	£28.31
Trurapi® 100units/ml 3ml cartridges	5 x 3ml cartridges	£21.42
NovoRapid® 100units/ml 3ml pre-filled FlexPen pens	5 x 3ml pens	£30.60
Trurapi® 100units/ml 3ml pre-filled Solostar pens	5 x 3ml pens	£19.82
NovoRapid® 100units/ml 10ml vials	1 x 10ml vial	£14.08
Trurapi® 100units/ml 10ml vials	1 x 10ml vial	£11.97

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

Prescribing information

- All insulin prescriptions should include the brand name, the strength of the insulin and the administration device to ensure continuity of supply.
 - The Trurapi® pre-filled pen device is a SoloStar® pen, which is the same as all other Sanofi insulins.
 - Trurapi® cartridges should only be used with JuniorSTAR® pens (capable of half-unit dosing), and Tactipen®, AllStar® or AllStar PRO® pens (which all deliver insulin in single unit increments). If prescribing Trurapi® cartridges, an appropriate durable pen will also need to be supplied with the initial prescription. Trurapi® cartridges are not compatible with Novo Nordisk durable pens.
 - Transferring a patient from NovoRapid® to Trurapi® can initially be done unit-for-unit based on the existing NovoRapid® dose. Further dose adjustments may be required based on blood glucose readings.
- Trurapi® is a black triangle drug as it is relatively new to market.
- Trurapi® is **NOT** considered interchangeable with Fiasp®, which can still be used where indicated (e.g., when a more rapid onset of action is required).

Implementation plan

- Communication of the Cheshire and Merseyside Trurapi® position statement to be undertaken by medicines management and pharmacy teams, clinical networks and Local Pharmaceutical Committees. Communication to be sent to all healthcare professionals involved in the care, including the supply of insulin, of patients with diabetes.
 - If clinically appropriate and in line with the switching guidance, patients can be switched from NovoRapid® to Trurapi® opportunistically or as part of planned care.
 - NHS Cheshire and Merseyside Place Medicines Management Teams will switch/facilitate the switch of existing patients in primary care on NovoRapid® to Trurapi® with appropriate counselling where this is clinically appropriate and in line with the detailed switching guidance.
 - Further detailed implementation plans will be developed and shared based on place discussions, skill mix and capacity.

Considerations for converting existing patients to Trurapi®

Patient can initially be switched from NovoRapid® to Trurapi® unit-for-unit based on the previous NovoRapid® dose (i.e., initial Trurapi dose = existing NovoRapid dose)^{4,5,8}. Patients should continue to monitor their blood glucose as usual and can continue to use their current insulin needles.

Note the following exclusion criteria for switching patients.

The following patient cohorts must **NOT** be switched from NovoRapid® to Trurapi®

- Patients requiring the functionality offered by a smart durable pen (e.g. NovoPen 6® / NovoPen Echo Plus®) such as electronic recording of doses and administrations;
- Patients prescribed a NovoRapid PumpCart® or NovoRapid® vials should only be switched by specialist diabetes teams if appropriate. They may also be prescribed back-up NovoRapid FlexPens® and cartridges for use in the event of pump failure, these should also only be switched by specialist diabetes teams;
- Patients prescribed NovoMix® (biphasic insulin aspart / insulin aspart with insulin aspart protamine) as this is **NOT** the same as NovoRapid®;
- Patients who have had a previous trial of Trurapi® or have recorded allergy to it, or any of the excipients;
- Patients on the Fiasp® brand of insulin aspart as this is **NOT** considered interchangeable with Trurapi®;

Additional precautions should be taken before switching the following cohorts from NovoRapid® to Trurapi®

- Patients with cognitive impairment, dementia or a learning disability who self-administer their insulin should be assessed individually to ascertain appropriateness before switching to Trurapi®.
- Pregnant patients currently prescribed NovoRapid® should **NOT** be switched until post-partum. For treatment of new diabetes diagnosis during pregnancy Trurapi® is the first line insulin aspart if required.

Further information

See Appendices for supportive example templates to facilitate switch programmes. These can be adapted for local use.

Resources for healthcare professionals:

[Trurapi® summary of product characteristics](#)

[Sanofi campus - Trurapi®](#)

Resources for patients:

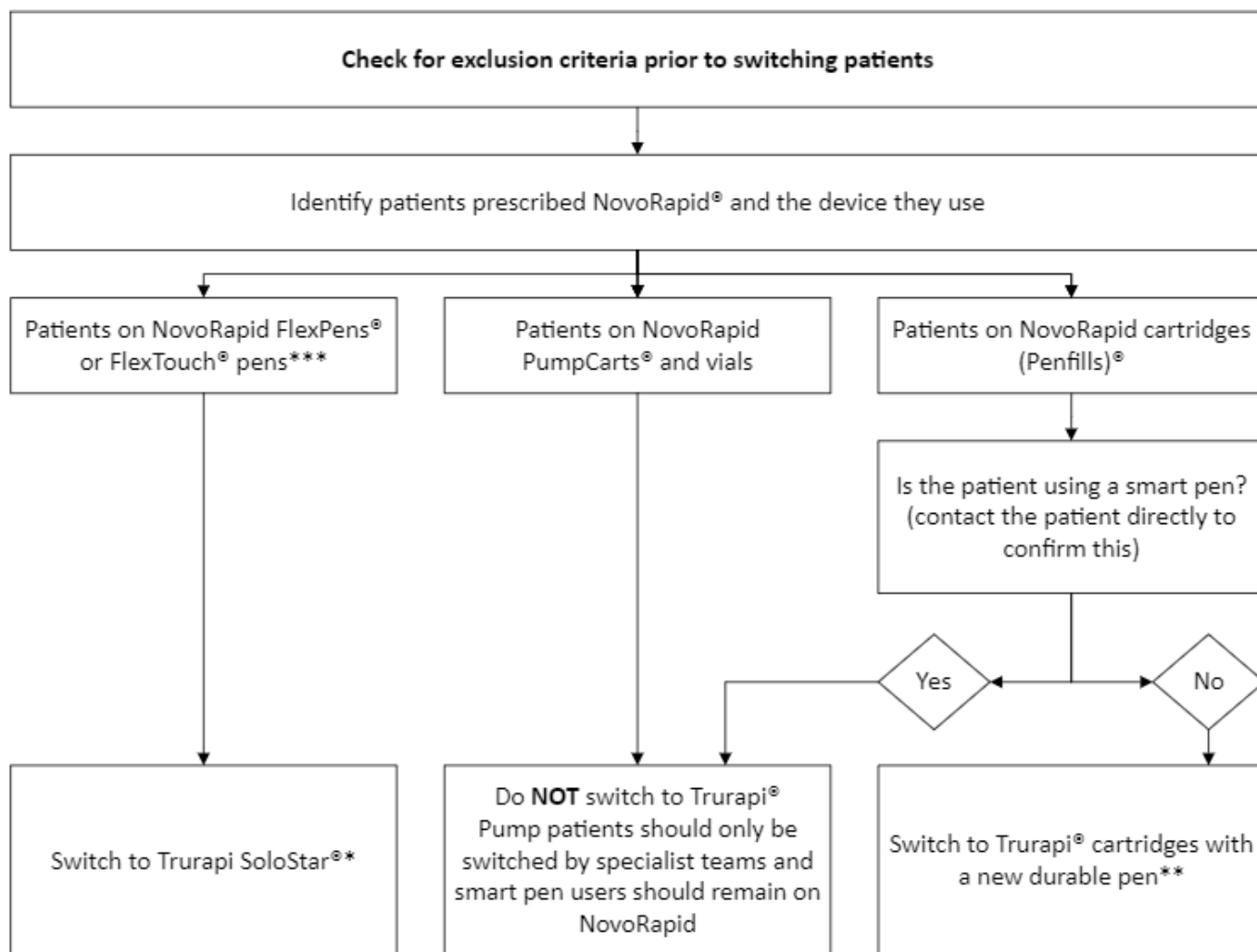
[Sanofi diabetes patient website - Trurapi®](#)

<https://www.patients-association.org.uk/switchingtobiosimilars>

References

1. Medicines and Healthcare Products Regulatory Agency. [Guidance on the licensing of biosimilar products](#). Last updated 22 November 2022 [accessed 07 June 2022].
2. European Medicines Agency. [Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU](#). Last updated 21 April 2023 [accessed 07 June 2022].
3. NHS England. [What is a biosimilar medicine?](#) Last updated 21 February 2023. [accessed 07 June 2022].
4. Kapitza C, Nosek L, Schmider W *et al*. Single-dose euglycemic clamp study demonstrating pharmacokinetic and pharmacodynamics similarity between SAR341402 insulin aspart and US- EU-approved versions of insulin aspart in subjects with type 1 diabetes. *Diabetes Technology and Therapeutics*. 2020; 22(4): 278–284. DOI: 10.1089/dia.2019.0351.
5. Garg SK, Wernicke-Panten K, Wardecki M *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 randomised open-label trial (GEMELLI 1). *Diabetes Technology and Therapeutics*. 2020; 22(2): 85–95. DOI: 10.1089/dia.2019.0382.
6. NHS England. [National medicines optimisation opportunities 2023/24](#). Last updated 19 October 2023 [accessed 07 June 2022].
7. NHS Business Services Authority. [Dictionary of medicines and devices \(dm+d\)](#). [accessed 07 June 2024].
8. Sanofi Campus. [Trurapi](#). Last updated April 2024 [accessed 19th July 2024]

Appendix 1: Flowchart for switching patients on NovoRapid® to Trurapi®



*When switching patients to **Trurapi SoloStar®**, the patient should be informed, and a prescription issued. It would be good practice to include the phrase “This is equivalent to NovoRapid®” on the initial prescription for reassurance.

When switching patients to **Trurapi cartridges®, the patient should be informed, and a prescription issued. It would be good practice to include the phrase “This is equivalent to NovoRapid®” on the initial prescription for reassurance.

Patients prescribed Trurapi® cartridges will also need to be supplied with **two** durable pen devices, noting that:

- (1) If using whole units then they should be offered **two** AllStar PRO® pens;
- (2) If using half units then they should be offered **two** JuniorSTAR® pens;
- (3) The durable pen device they are given should be a different colour to the insulin pen they use for their long-acting insulin (AllStar PRO® pens are available in blue and silver and JuniorSTAR® pens are available in blue, red and silver).

Contact either Elizabeth Dibbert (elizabeth.dibbert@sanofi.com) and/or Danielle Ogilby (danielle.ogilby@sanofi.com) for supplies of Sanofi durable pens and patient information leaflets.

***NovoRapid FlexTouch® pens are being discontinued in March 2025 and there are no alternative device for patients with reduced dexterity.

Patients can continue to use their current insulin needles which are compatible with Sanofi products.

Appendix 2 – Example letter templates to inform patients of the switch

Dear Patient,

R.E. change in brand of your short acting insulin from NovoRapid® to Trurapi®

You are currently prescribed NovoRapid FlexPen® or NovoRapid FlexTouch® insulin aspart as part your diabetes management.

Another brand of insulin aspart is now available called Trurapi® which is considered equivalent to NovoRapid®. Trurapi® is manufactured by Sanofi which is large pharmaceutical company with lots of experience with diabetes and insulin. Trurapi® is better value for money for the NHS and experts (nationally and locally) agree that patients can be safely switched between these brands.

We are therefore recommending switching your short acting insulin from:

NovoRapid FlexPen® or NovoRapid FlexTouch® (prefilled, disposable pen)

to

Trurapi SoloStar® (pre-filled, disposable pen)

There will be no need to change your dose, and this will not have any negative impact on your diabetes control. You should continue to administer your insulin at the **same dose** and in the same way.

Unless we hear from you to discuss any concerns, your next supply of insulin will be Trurapi®.

Prior to switching to Trurapi®:

- Prepare to use your new insulin by watching a demonstration video of how to use the Trurapi SoloStar® device at <https://www.mysanofiinsulin.co.uk/trurapi/> (or scan the QR code). If you do not have access to the internet, instructions will be provided within the packaging of your new Trurapi® insulin. Also, your GP or community pharmacist can help you with any questions.
- Use all existing supplies of NovoRapid® before switching to Trurapi®. Ensure that you obtain supplies of your new insulin at least a week before you run out of your NovoRapid®.
- Continue to monitor your blood glucose in your usual way.
- If you adjust your insulin dose according to blood glucose readings and diet continue to do so in your usual way.



Your current insulin needles will fit your new Trurapi SoloStar® pen.

If you have any concerns about this switch, then please contact your GP, practice pharmacist, or community pharmacist who can provide further information.

Yours faithfully,

Frequently asked questions

Who manufactures Trurapi®?

Trurapi® is manufactured by Sanofi which is large pharmaceutical company with lots of experience in diabetes and insulin. They make several other commonly used insulins including Lantus®.

What is a 'biosimilar' insulin?

A biosimilar insulin is new version of an existing insulin product made by a different company. It is essentially the same and has been extensively tested to ensure that it has the same effects and that it is as safe as the original product. Biosimilar insulins are much more cost effective than the original products for the NHS but won't negatively impact on your diabetes control. For more information about biosimilar medicines, visit <https://www.patients-association.org.uk/switchingtobiosimilars> or scan the QR codes below.



Biosimilar patient
information leaflet



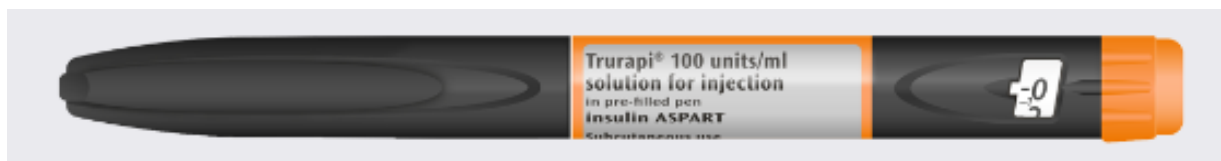
Biosimilar patient
video

Is Trurapi® as effective as NovoRapid®?

Trurapi® has undergone a detailed head-to-head comparison with NovoRapid® which has shown that there are no clinically significant differences between them, and that any previously proven data for NovoRapid® also apply to Trurapi®. Trurapi® has been approved for use within the UK on the basis that it is no different from NovoRapid®.

What do Trurapi SoloStar® devices look like?

Trurapi SoloStar® devices are prefilled, disposable pens similar in appearance to Sanofi's other insulins (like Lantus®) but they are orange in colour. A picture of the Trurapi SoloStar® pen is shown below.



Dear Patient,

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We are therefore recommending switching your short acting insulin from:

NovoRapid® cartridges
to
Trurapi® cartridges (for use with an AllStar PRO® durable pen)

There will be no need to change your dose, and this will not have any negative impact on your diabetes control. You should continue to administer your insulin at the **same dose** and in the same way.

Unless we hear from you to discuss any concerns, your next supply of insulin will be Trurapi®.

Prior to switching to Trurapi®:

- Collect your new AllStar PRO® durable pen from your GP surgery (you should collect two devices so that you have a spare). Trurapi® cartridges are NOT compatible with your current durable pen.
- The AllStar PRO® durable pen devices are available in two colours (blue and silver) and you can request a particular colour. It is important that the pen you use for your Trurapi® is a different colour from the pen you use for your long-acting insulin.
- If you administer half units of insulin, please inform your GP surgery because you will need a JuniorSTAR® durable pen instead (not an AllStar PRO®).
- Prepare to use your new insulin by watching a demonstration video of how to use the Trurapi® cartridge and AllStar PRO® (or JuniorSTAR®) durable pen at <https://www.mysanofiinsulin.co.uk/trurapi/> (or scan the QR code). This website also contains information leaflets you may find helpful. If you do not have access to the internet, instructions will be provided within the packaging of your new Trurapi® insulin. Also, your GP or community pharmacist can help you with any questions.
- Use all existing supplies of NovoRapid® before switching to Trurapi®. Ensure that you obtain supplies of your new insulin at least a week before you run out of your NovoRapid®.
- Continue to monitor your blood glucose in your usual way.
- If you adjust your insulin dose according to blood glucose readings and diet continue to do so in your usual way.



Your current insulin needles will fit your new AllStar PRO® pen.

If you have any concerns about this switch, then please contact your GP, practice pharmacist, or community pharmacist who can provide further information.

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information leaflet



Biosimilar patient
video

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What do Trurapi® cartridges and AllStar PRO® pen devices look like?

Trurapi® cartridges are similar to NovoRapid® cartridges in appearance but are NOT compatible with Novo Nordisk® durable pens. Trurapi® cartridges should only be used with Sanofi durable pens (such as AllStar PRO® and JuniorSTAR® pens). A picture of the cartridge and the AllStar PRO® durable pen device is shown below.

