

This document is designed to provide factual information about Trurapi

Prescribing Information is available on page 4 of this document

SUMMARY

Product Type	Biosimilar Rapid Acting Insulin
Brand Name	Trurapi
Generic Name	Insulin Aspart
Strength and Form	100 units/ml in vial, cartridge and pre-filled pen
Manufacturer	Sanofi
Other Information	Biosimilar to NovoRapid

PACKAGING & LABELLING

Does the product have a UK marketing authorisation?	Yes
Is the medicine's generic name clearly identifiable in English on the packaging	Yes
Is other critical information also clearly identifiable in English on the packaging?	Yes
Is the critical information above clear on all sides of the packaging as well as on both primary (e.g. the pen) and secondary (e.g. the carton) packaging?	Yes
Is the generic name also suitably prominent?	Yes
Is pharmaceutical information such as the batch number, expiry date, and storage conditions clear and unambiguous on the packaging?	Yes
Are all generic constituents clearly stated on the packaging?	Yes
Is the expression of strength stated on the packaging consistent with prescribing practice?	Yes
Does the packaging encourage (or at the least not hinder) differentiation between a range of products from a single supplier, or between different products from different suppliers?	Yes. Trurapi pre-filled pens are dark grey with orange button The packaging is white with orange Sanofi Insulins have distinct colour packaging for each insulin

INFORMATION WITH PRODUCT

Is an English language patient information leaflet available with the product?	Yes
Is English language prescribing information available for the product?	Yes
Is appropriate technical information available in English at the point of care to guide calculations, preparation, and administration?	Yes - Sanofi provide a patient booklet and insulin passport
Does the product information only contain positive statements about use?	Appropriate special warnings and precautions for use are included in the patient information leaflet in the pack

PRESCRIBING RISKS

Is the product an additional treatment option, or is it replacing another product or drug?	Trurapi is a biosimilar to NovoRapid (Insulin Aspart)
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Are there particular issues associated with non-familiarity or confusion with existing treatments?	No additional issues other than those already associated with insulin use and biosimilar medicines
Is the dosing and prescribing of the medicine complex?	Dosing and prescribing is the same as any other rapid acting insulins
Who will prescribe the item? And is the prescribing of the medicine likely to be within the normal scope of practice for expected prescribers?	All healthcare professionals who currently prescribe bolus insulins within the normal scope of practice.
Is the process of prescribing likely to be familiar to the prescriber?	Yes
Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented?	In line with originator insulin (NovoRapid)

RISK MANAGEMENT

Has the medicinal product (or any similar product) been the subject of any previous medicines safety alerts (such as an NPSA report, description as a never event, or inclusion on an MHRA drug safety bulletin)?	All insulins remain a focus for patient safety and have been subject to medicines safety alerts
Is the medicine under intensive regulatory surveillance?	No
Are new or amended clinical or laboratory monitoring requirements associated with the introduction of the medicinal product?	No
Does the medicine have the potential to cause significant harm in deliberate or inadvertent overdose? And if it does, are suitable reversibility and antidote strategies available? Or alternatively are clinical management strategies in such circumstances defined?	As with all insulin, there is potential for harm and overdose Existing strategies for rapid acting insulin would be appropriate for Trurapi
Where necessary, is tailored patient facing information available to support safe use of the medicine? For example, are steroid or lithium cards present if necessary?	Patient information leaflets/booklet and insulin passport cards are provided by the manufacturer

PREPARATION CALCULATION & LABELLING

Are there current known operator safety issues with the drug?	No
Is the medicine of a class where operator safety issues might be a concern? Is the medicine subject to COSHH regulations, for example?	No further concerns other than those associated with insulin use

ADMINISTRATION

Is administration of the product in any way complex?	Same as originator insulin (NovoRapid)
Is the route of administration of the product intrinsically high risk (such as intrathecal)?	Same as originator insulin (NovoRapid)
Does administration require the use of a device and/or disposables?	Patients will either self-administer (if appropriate) using either the SoloStar Pen Device or the Cartridges in an appropriate Sanofi device. A healthcare professional using an insulin syringe can withdraw and administer to a patient from a vial
Where the product requires the use of a device and/or disposables are there any issues related to their use?	Same as originator insulin (NovoRapid)
For injectable medicines, how safety critical is the rate of administration? And what mechanisms are in place to ensure it is correct?	Same as originator insulin (NovoRapid)

For injectable medicines, is any specific monitoring required during administration?	Same as originator insulin (NovoRapid)
If specific monitoring is required, is it practicable and achievable?	Same as originator insulin (NovoRapid)

SUPPLY CHAIN

Is the product readily and reliably available from a recognised supplier?	Sanofi manufacturer and supply a range of insulins to the NHS
Are expiry dates (both for the product in its original form, and in-use as necessary) available and clear?	Yes
Are there any specific storage requirements for the product?	Cold chain storage, as per all insulins
Are there any other issues in relation to storage? For example, is bulk and the space necessary to store the product an issue?	Same as originator insulin (NovoRapid)
Are there any issues in relation to security of storage? For example, is there a likelihood of misappropriation?	Same as originator insulin (NovoRapid)
Overall, consider whether the storage requirements can likely be met?	Same as originator insulin (NovoRapid)

DISPOSAL

Does the product pose any special risks during disposal to either the user or staff?	Same as originator insulin (NovoRapid)
Are there any specific disposal requirements of the product?	Same as originator insulin (NovoRapid)

SETTING TO BE USED IN

Is the product for use in a highly specialist environment? For example, in neonates, fluid restricted patients, or those in critical care scenarios?	Same as originator insulin (NovoRapid)
Where the product is highly specialist, is there the potential that it will be used outside such an environment? And if so have issues associated with such use been identified and addressed?	Same as originator insulin (NovoRapid)
Is the medicine one which is likely to be used across other boundaries of care?	Same as originator insulin (NovoRapid)
If the medicine is used across care boundaries, have issues associated with such use been identified and addressed?	Same as originator insulin (NovoRapid)
Is the medicine one for which self-administration by patients is a possibility? Have any issues associated with such use been identified and addressed?	Same as originator insulin (NovoRapid)
Where the manipulation of the product is complex, is the environment in which it is to be prepared conducive to its safe use? That is, will it be as free as possible from distractions and is it an otherwise suitable environment for complex manipulation?	Same as originator insulin (NovoRapid)

Trurapi® is manufactured in Germany and quality checked & released at Sanofi-Aventis Deutschland GmbH in Frankfurt, Germany. Trurapi® is readily available from mainline wholesalers including AAH and Phoenix. Sanofi have sufficient stock in the UK and a robust supply plan in place to ensure continued supply of Trurapi®. These supply plans are constantly reviewed and updated.

Prescribing Information: Trurapi (Insulin aspart 100 units/ml)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Trurapi 100 units/ml (equivalent to 3.5 mg) solution for injection in a vial, each containing 10ml of solution for injection, equivalent to 1000 units. Trurapi 100 units/ml solution for injection in a cartridge or in a pre-filled pen, each containing 3ml of solution for injection, equivalent to 300 units insulin aspart.

Indication: The treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

Dosage and Administration: Trurapi is a rapid-acting insulin analogue, normally used in combination with intermediate-acting or long-acting insulin. Trurapi should not be mixed with any other insulin. The dosage should be determined by the physician in accordance with individual patient needs. Blood glucose monitoring and insulin dose adjustments are recommended to achieve optimal glycaemic control. The individual insulin requirement in adults and children is usually 0.5–1.0 unit/kg/day. In a basal-bolus treatment regimen 50–70% of this requirement may be provided by Trurapi and the remainder by intermediate-acting or long-acting insulin. Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness (see Precautions and Warnings).

Transfer from other insulin medicinal products: When transferring from other insulin medicinal products, adjustment of the Trurapi and basal insulin dose may be necessary as Trurapi has a faster onset and a shorter duration of action than soluble human insulin. When injected subcutaneously into the abdominal wall, the onset of action will occur within 10–20 minutes of injection. The maximum effect is exerted 1–3 hours after the injection with duration of action of 3–5 hours. **Subcutaneous administration:** This should be in the upper arms, thighs, buttocks or abdomen and injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites and faster onset of action of insulin aspart is maintained regardless of the injection site. The duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. Due to the faster onset of action, insulin aspart should generally be given immediately before a meal. When necessary insulin aspart can be given soon after a meal.

Trurapi in cartridges: only suitable for subcutaneous injections from a specified type of reusable pen. **Trurapi in pre-filled pen:** only suitable for subcutaneous injections.

Trurapi in pre-filled pen delivers 1-80 units in increments of 1 unit. Patients must visually verify the dialled units on the dose counter of the pen. Therefore, the requirement for patients to self-inject is that they can read the dose counter on the pen. Patients who are blind or have poor vision must be instructed to always get help/assistance from another person who has good vision and is trained in using the insulin device.

Administration via an insulin infusion pump (Trurapi vials only): CSII should be administered in the abdominal wall and infusion sites should be rotated. Patients using CSII should be comprehensively instructed in the use of the pump system and use the correct reservoir and tubing for the pump. The infusion set (tubing and cannula) should be changed in accordance with the instructions in the product information supplied with the infusion set. An alternative insulin delivery method should be available in case of pump system failure. **Intravenous administration (Trurapi vials only):** This should be carried out by physicians or other healthcare staff following normal clinical practice for intravenous injections. Monitoring of blood glucose is necessary during insulin infusion.

Special Populations: Elderly patients (≥ 65 years old) and renal/hepatic impairment: Trurapi can be used in elderly patients and patients with renal or hepatic impairment; glucose monitoring should be intensified and dose adjusted on an individual basis. **Paediatric population:** Trurapi can be used in adolescents and children aged 1 year and above in preference to soluble human insulin when a rapid onset of action might be beneficial, for example, in the timing of the injections in relation to meals. The safety and efficacy in children below 1 year of age have not been established.

Contraindications: Hypersensitivity to insulin aspart or to any of the excipients.

Precautions and Warnings: Traceability: The name and the batch number of the administered product should be clearly recorded to improve the traceability.

Injection technique: Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medicinal products may be considered.

Hyperglycaemia: Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. Usually the first symptoms of hyperglycaemia develop gradually over a period of hours or days. They include thirst, increased frequency of urination, nausea, vomiting, drowsiness, flushed dry skin, dry mouth, loss of appetite as well as acetone odour of breath. In type 1 diabetes, untreated hyperglycaemic events eventually lead to diabetic ketoacidosis, which is potentially lethal.

Hypoglycaemia: Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. Especially in children, care should be taken to match insulin doses (especially in basal-bolus regimens) with food intake, physical activities and current blood glucose level in order to minimise the risk of hypoglycaemia. Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement and in case of hypoglycaemia or if hypoglycaemia is suspected insulin aspart must not be injected. After stabilisation of patient's blood glucose adjustment of the dose should be considered. Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia, and usual warning symptoms may disappear in patients with longstanding diabetes, so patients should be advised accordingly. Hypoglycaemia in rapid-acting insulin analogues may occur earlier after an injection when compared with soluble human insulin and since insulin aspart should be administered immediately in relation to a meal, the rapid onset should be considered in patients with concomitant diseases or treatment where a delayed absorption of food might be expected. Concomitant illness usually increases the patient's insulin requirements and concomitant diseases in the kidney, liver or affecting the adrenal, pituitary or thyroid gland can require changes in the insulin dose. When patients are transferred between different types of insulin medicinal products, the early warning symptoms of hypoglycaemia may change or become less pronounced than those experienced with their previous insulin. **Transfer from other insulin medicinal products:** Should be done under strict medical supervision. If dose adjustment is needed, it may occur with the first dose or during the first few weeks or months. Close

glucose monitoring is recommended during the transfer and in the initial weeks thereafter. Injection site reactions (including lipodystrophy and cutaneous amyloidosis): As with any insulin therapy, injection site reactions may occur and include pain, redness, hives, inflammation, bruising, swelling and itching. Continuous rotation of the injection site within a given area reduces the risk of developing these reactions and these usually resolve in a few days to a few weeks. Continuous rotation of the injection site also reduces the risk of developing lipodystrophy and cutaneous amyloidosis. Blood glucose monitoring is recommended after the change in the injection site due to risk of hypoglycaemia, and dose adjustment of antidiabetic medications may be considered. On rare occasions, injection site reactions may require discontinuation of insulin aspart. Combination with pioglitazone: Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Medication errors: Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between Trurapi and other insulin medicinal products. Insulin antibodies: Insulin administration may cause insulin antibodies to form, which in rare cases may necessitate adjustment of the insulin dose to correct a tendency to hyper- or hypoglycaemia. Travel: Patients should seek physician advice before travelling to different time zones as this may mean that the insulin and meals may be taken at different times. Sodium: This medicinal product contains less than 1 mmol sodium (23mg) per dose, that is to say essentially "sodium free". Interactions: Several medicinal products are known to interact with the glucose metabolism. Substances that may reduce insulin requirements: Oral antidiabetic medicinal products, monoamine oxidase inhibitors (MAOI), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulphonamides. Substances that may increase insulin requirements: Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol. Other potential interactions of note: Octreotide/lanreotide may either increase or decrease the insulin requirement. Beta-blockers may mask the symptoms of hypoglycaemia. Alcohol may intensify or reduce the hypoglycaemic effect of insulin. Pregnancy and Breast-Feeding: Pregnancy: It is essential to maintain good control of the insulin-treated (insulin-

dependent or gestational diabetes) patient throughout pregnancy and intensified blood glucose control and monitoring of pregnant women with diabetes are recommended throughout pregnancy and when contemplating pregnancy. Data from two randomised controlled clinical trials do not indicate any adverse reaction of insulin aspart on pregnancy or on the health of the fetus/newborn when compared to human insulin. Breast-feeding: There are no restrictions on treatment with Trurapi during breast-feeding, but the dose may need to be adjusted.

Adverse Reactions: Adverse reactions observed in patients using Trurapi are mainly due to the pharmacologic effect of insulin. Hypoglycaemia is the most frequent adverse reaction and may occur if the insulin dose is too high in relation to the insulin requirement. Uncommon ($\geq 1/1,000$ to $< 1/100$): urticaria, rash, eruptions, refraction disorders, diabetic retinopathy, injection site reactions such as lipodystrophy and oedema that can be reduced by continuous rotation of the injection site. Rare ($\geq 1/10,000$ to $< 1/1,000$): Peripheral neuropathy (painful neuropathy). Very rare ($< 1/10,000$): anaphylactic reactions which can potentially be life threatening. Frequency not known: cutaneous amyloidosis. Special populations: The frequency, type and severity of adverse reactions observed in the paediatric population, elderly patients and patients with renal or hepatic impairment do not indicate any differences to the broader experience in the general population. *Prescribers should consult the SPC in relation to other adverse reactions.*

Legal Category: POM

Marketing Authorisation (MA) Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK.

GB List price and MA numbers: *Trurapi 100 units/ml solution for injection in vial 1 x 10ml: £11.97 – PLGB 04425/0891. Trurapi 100 units/ml solution for injection in cartridge 5 x 3ml: £19.82 – PLGB 04425/0885. Trurapi 100 units/ml solution for injection in pre-filled pen 5 x 3ml: £21.42 – PLGB 04425/0886.*

Further information is available from: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. **SmPC Date**: 29/03/2023

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK-drugsafety@sanofi.com