

Serious allergic reactions to Trurapi or one of its ingredients (called a systemic allergic reaction) is a very rare side effect but can potentially be life-threatening. It may affect up to 1 in 10,000 people.

Seek medical advice immediately:

- If signs of allergy spread to other parts of your body.
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.

If you notice any of these signs, seek medical advice immediately.

Other side effects

Skin changes at the injection site:

If you inject insulin too often at the same place, the fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect up to 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or nurse. These reactions can become more severe, or they may change the absorption of your insulin, if you inject in such a site.

Uncommon (may affect up to 1 in 100 people)

Signs of allergy: Local allergic reactions (pain, redness, hives, inflammation, bruising, swelling and itching) at the injection site may occur. These usually disappear after a few weeks of using your insulin. If they do not disappear, or if they spread throughout your body, talk to your doctor immediately (see also "Serious allergic reactions" above).

Vision problems: When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Swollen joints: When you start using insulin, water retention may cause swelling around your ankles and other joints. Normally this soon disappears. If not, talk to your doctor.

Diabetic retinopathy (an eye disease related to diabetes which can lead to loss of vision): If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

Rare side effects (may affect up to 1 in 1,000 people).

Painful neuropathy (pain due to nerve damage): If your blood sugar level improves very fast, you may get nerve-related pain. This is called acute painful neuropathy and is usually transient.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

Effects from diabetes

High blood sugar (hyperglycaemia)

High blood sugar may occur if you:

- Have not injected enough insulin.
- Forget to inject your insulin or stop using insulin.
- Repeatedly inject less insulin than you need.
- Get an infection and/or a fever.
- Eat more than usual.
- Exercise less than usual.

Warning signs of high blood sugar:

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed; dry skin; dry mouth and a fruity (acetone) smell of the breath.

What to do if you experience high blood sugar

- If you get any of the above signs: test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.
- These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death.

5. How to store Trurapi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Before the first use: store your Trurapi in a refrigerator (2°C - 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

After first opening: keep your Trurapi vial that you are using at room temperature (below 30°C) for a maximum of 4 weeks. Do not keep the vial that you are using in the fridge or freezer. Keep the vial in the outer carton in order to protect from light.

Do not use Trurapi vial if the solution is coloured or it has solid pieces in it. You must use it **only** if it looks like water. Check this each time you inject yourself.

Discard the needle after each injection.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Trurapi contains

- The active substance is insulin aspart. One ml of the solution contains 100 units of insulin aspart (equivalent to 3.5 mg). Each vial contains 10 ml of solution for injection, equivalent to 1,000 units of insulin aspart.
- The other ingredients are: phenol, metacresol, zinc chloride, polysorbate 20, sodium chloride, hydrochloric acid/sodium hydroxide and water for injections. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity (see "Trurapi contains sodium" in section 2).

What Trurapi looks like and contents of the pack

Trurapi solution for injection is a clear, colourless solution. Each vial contains 10 ml.

Trurapi in vial comes in a pack of 1 or 5 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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