

# Trurapi®

## 100 units/ml

### solution for injection in cartridge

#### insulin aspart

sanofi

Is this leaflet hard to see or read?  
Phone 0800 035 2525 for help.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.

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- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Trurapi is and what it is used for
2. What you need to know before you use Trurapi
3. How to use Trurapi
4. Possible side effects
5. How to store Trurapi
6. Contents of the pack and other information

#### 1. What Trurapi is and what it is used for

Trurapi is a modern insulin (insulin analogue) with a rapid-acting effect. Modern insulin products are improved versions of human insulin.

Trurapi is used to reduce the high blood sugar level in adults, adolescents and children aged 1 year and above with diabetes mellitus (diabetes). Diabetes is a disease where your body does not produce enough insulin to control the level of your blood sugar. Treatment with insulin aspart helps to prevent complications from your diabetes.

Insulin aspart will start to lower your blood sugar 10–20 minutes after you inject it, a maximum effect occurs between 1 and 3 hours after the injection and the effect lasts for 3–5 hours. Due to this short action insulin aspart should normally be taken in combination with intermediate-acting or long-acting insulin preparations.

#### 2. What you need to know before you use Trurapi

##### Do not use Trurapi

- If you are allergic to insulin aspart, or any of the other ingredients of this medicine (listed in section 6).
- If you suspect hypoglycaemia (low blood sugar) is starting (see “Summary of serious and very common side effects” in section 4).
- If the cartridge or the device containing the cartridge is dropped, damaged or crushed.
- If it has not been stored correctly or been frozen (see “How to store Trurapi” in section 5).
- If the insulin does not appear clear and colourless.

If any of these applies, do not use Trurapi. Talk with your doctor, nurse or pharmacist for advice.

##### Before using Trurapi

- Check the label to make sure it is the right type of insulin.
- Always check the cartridge, including the rubber plunger at the bottom of the cartridge. Do not use it if any damage is seen or if the rubber plunger has been drawn above the white label band at the bottom of the cartridge. This could be a result of leakage of insulin. If you suspect the cartridge is damaged, take it back to your supplier. See your pen manual for further instructions.
- Always use a new needle for each injection to prevent contamination.
- Needles and pens must not be shared.
- Trurapi is only suitable for injecting under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method.

##### Warnings and precautions

Record the brand name (“Trurapi”) and Lot number (included on the outer cartons and labels of each cartridge) of the medicine you are using and provide this information when reporting any side effects.

##### Skin changes at the injection site

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see “How to use Trurapi”). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Some conditions and activities can affect your need for insulin. Consult your doctor:

- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- If you exercise more than usual or if you want to change your usual diet, as this may affect your blood sugar level.
- If you are ill, carry on taking your insulin and consult your doctor.
- If you are going abroad, travelling over time zones may affect your insulin needs and the timing of your injections.

##### Children and adolescents

Do not give this medicine to children below 1 year of age since no clinical trials have been carried out in children below the age of 1 year.

##### Other medicines and Trurapi

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines affect your blood sugar level and this may mean that your insulin dose has to change. Listed below are the most common medicines which may affect your insulin treatment.

##### Your blood sugar level may fall (hypoglycaemia) if you take:

- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
- Salicylates (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulphonamides (used to treat infections).

##### Your blood sugar level may rise (hyperglycaemia) if you take:

- Oral contraceptives (birth control pills)
- Thiazides (used to treat high blood pressure or excessive fluid retention)
- Glucocorticoids (such as ‘cortisone’ used to treat inflammation)
- Thyroid hormones (used to treat thyroid gland disorders)
- Sympathomimetics (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma)
- Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body’s metabolic processes)
- Danazol (medicine acting on ovulation).

Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise low blood sugar.

##### Pioglitazone (tablets used for the treatment of type 2 diabetes)

Some patients with long-standing type 2 diabetes and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

If you have taken any of the medicines listed here, tell your doctor, nurse or pharmacist.

##### Insulin aspart and alcohol

If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

##### Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Insulin aspart can be used during pregnancy. Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.

There are no restrictions on treatment with insulin aspart during breast-feeding.

Ask your doctor, nurse or pharmacist for advice before using this medicine while pregnant or breast-feeding.

##### Driving and using machines

Please ask your doctor whether you can drive a car or use a machine:

- If you have frequent hypoglycaemia.
- If you find it hard to recognise hypoglycaemia.

If your blood sugar is low or high, your concentration and ability to react might be affected and therefore also your ability to drive or use a machine. Bear in mind that you could endanger yourself or others.

Trurapi has a rapid onset of effect therefore if hypoglycaemia occurs, you may experience it earlier after an injection when compared to soluble human insulin.

##### Trurapi contains sodium

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially “sodium-free”.

#### 3. How to use Trurapi

##### Dose and when to use your insulin

Always use your insulin and adjust your dose exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Insulin aspart is generally used immediately before a meal. Eat a meal or snack within 10 minutes of the injection to avoid low blood sugar. When necessary, Trurapi can be given soon after a meal (see “How and where to inject” below for information).

Do not change your insulin unless your doctor tells you to. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor.

##### Use in children and adolescents

Insulin aspart can be used in adolescents and children aged 1 year and above instead of soluble human insulin when a rapid onset of effect is preferred. For example, when it is difficult to dose the child in relation to meals.

##### Use in special patient groups

If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

##### How to use and where to inject

Trurapi is for injection under the skin (subcutaneously). You must never inject yourself directly into a vein (intravenously) or muscle (intramuscularly). Trurapi 100 units/ml in cartridges is only suitable for injecting under the skin using a reusable pen. Speak to your doctor if you need to inject your insulin by another method.

With each injection, change the injection site within the particular area of skin that you use. This may reduce the risk of developing lumps or skin pitting (see section 4 “Possible side effects”). The best places to give yourself an injection are: the front of your waist (abdomen), the upper arm or the front of your thighs. The insulin will work more quickly if you inject into the front of your waist (abdomen). You should always measure your blood sugar regularly.

- To ensure you get the accurate dose, the Trurapi cartridges are to be used only with the following pens:
  - JuniorSTAR which delivers doses in steps of 0.5 units
  - Tactipen, AllStar and AllStar PRO which deliver doses in steps of 1 unit.
 Not all of these pens may be marketed in your country.
- Always carry a spare cartridge in case it is lost or damaged.

##### How to inject Trurapi

- Inject the insulin under the skin. Use the injection technique advised by your doctor or nurse and as described in your pen manual.
- Keep the needle under your skin for at least 10 seconds. Keep the dose button held in until the needle has been released from the skin. This will ensure you get your full dose.
- Remove and discard the needle after each injection. Do not store Trurapi with the needle attached. Otherwise the liquid may leak out which can cause inaccurate dosing.



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- Always use a new needle for each injection. This helps stop blocked needles, contamination and infection.

##### If you use more insulin than you should

If you use too much insulin your blood sugar gets too low (hypoglycaemia) (see “Summary of serious and very common side effects” in section 4).

##### If you forget to use your insulin

If you forget to use your insulin your blood sugar may get too high (hyperglycaemia) (see “Effects from diabetes” in section 4).

##### If you stop using your insulin

Do not stop using your insulin without speaking with a doctor, who will tell you what needs to be done. This could lead to very high blood sugar (severe hyperglycaemia) and ketoacidosis (see “Effects from diabetes” in section 4).

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### Summary of serious and very common side effects

**Low blood sugar (hypoglycaemia)** is a very common side effect. It may affect more than 1 in 10 people.

##### Low blood sugar may occur if you:

- Inject too much insulin.
- Eat too little or miss a meal.
- Exercise more than usual.
- Drink alcohol (see “Insulin aspart and alcohol” in section 2).

##### Signs of low blood sugar:

Cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

Severe low blood sugar can lead to unconsciousness. If prolonged severe low blood sugar is not treated, it can cause brain damage (temporary or permanent) and even death. You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon you will need glucose or a sugar snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

##### What to do if you experience low blood sugar:

- If you experience low blood sugar, eat glucose tablets or another high sugar snack (e.g. sweets, biscuits, fruit juice). Measure your blood sugar if possible and rest. Always carry glucose tablets or high sugar snacks with you, just in case.

- When symptoms of low blood sugar have disappeared or when blood sugar level is stabilised, continue insulin treatment as usual.
- If you have such a low blood sugar that it makes you pass out, if you have had need for injection of glucagon, or if you have experienced many incidents of low blood sugar, talk with a doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Tell relevant people that you have diabetes and what the consequences may be, including the risk of passing out (become unconscious) due to low blood sugar. Let them know that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink due to risk of suffocation.

**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** (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](http://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 cartridge in the outer carton in order to protect from light.

Keep your cartridge in use at room temperature (below 30°C) for a maximum of 4 weeks. Do not put it near heat or in the sun. Do not keep your pen with the inserted cartridge you are using in the fridge. The pen with the inserted cartridge should not be stored with the needle attached. Keep the pen cap on the pen to protect it from light.

Do not use Trurapi, if it 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.

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 (equivalent to 3.5 mg) of insulin aspart. Each cartridge contains 3 ml of solution for injection, equivalent to 300 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 cartridge contains 3 ml.

Do not refill the cartridge. Once empty, it must be disposed of.

If you are treated with Trurapi in cartridge and another insulin in cartridge, you should use the insulin delivery systems recommended by each manufacturer, one for each type of insulin.

The Trurapi cartridges come in a pack of 5 or 10 cartridges. Not all pack sizes may be marketed.

## Marketing Authorisation Holder

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## Manufacturer

Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.

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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