

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

TRURAPI® Cartridges (pronounced) troo-RA-pee

Insulin aspart injection

Cartridges are for use ONLY with AllStar® PRO and JuniorSTAR® pens. Please refer to the JuniorSTAR and AllStar PRO pen instructions for use leaflet supplied with the pens.

Read this carefully before you start taking **TRURAPI** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRURAPI**.

Contact your doctor, Diabetes Nurse Educator or pharmacist if you have any questions about this drug.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist. If you have trouble reading this, ask a family member or a friend for help.

TRURAPI is a biosimilar biologic drug (biosimilar) to the reference biologic drug -NovoRapid®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Hypoglycemia (low blood sugar) is the most common adverse effect of insulin, including TRURAPI.
- If hypoglycemia or hyperglycemic reactions are not treated they can result in the loss of consciousness, coma or death.
- Glucose monitoring is recommended for all patients with diabetes.
- Any change of insulin should be made cautiously and only under medical supervision. This may result in dosage adjustment.
- TRURAPI should be given immediately before a meal because of the fast onset of action (start of the meal should be not more than 5-10 minutes after injection). (see “How to take TRURAPI”)
- Never inject your insulin directly into a vein.
- TRURAPI should not be used if it is not water-clear and colourless.

What is TRURAPI used for?

- The treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia (high blood sugar).

How does TRURAPI work?

- TRURAPI is an insulin analogue used to treat diabetes.
- TRURAPI will start to lower your blood sugar 10-20 minutes after you take it, it has a maximum effect between 1 and 3 hours and the effects last for 3-5 hours. Due to this short action TRURAPI should normally be taken in combination with intermediate-acting or long-acting insulin preparations.

What are the ingredients in TRURAPI?

Medicinal ingredients: Insulin aspart

Non-medicinal ingredients: Hydrochloric acid, metacresol, phenol, polysorbate 20, sodium chloride, sodium hydroxide, water for injection, zinc chloride

TRURAPI comes in the following dosage forms:

Solution for Injection, 100 Units/mL

Do not use TRURAPI if:

- You feel a hypoglycemic reaction (low blood sugar) coming on. (see “What are possible side effects from TRURAPI?” for more about hypoglycemia).
- You are allergic (hypersensitive) to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction. (see “What are possible side effects from TRURAPI?”)
- The TRURAPI or Sanofi Insulin Delivery Device containing the cartridge/JuniorSTAR and AllStar PRO is dropped, damaged or crushed; there is a risk of leakage of insulin.
- The insulin has not been stored correctly or if it has been frozen. (see “How to store TRURAPI”)
- The insulin does not appear water-clear and colourless.

Do not refill a TRURAPI cartridge.

TRURAPI cartridges are designed to be used with JuniorSTAR and AllStar PRO Insulin Delivery Devices.

As a precautionary measure, you should carry an extra pen, insulin cartridges and needles.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRURAPI. Talk about any health conditions or problems you may have, including if you:

- Have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
- Drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
- Have an infection, fever or have had an operation you may need more insulin than usual.
- Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
- Exercise more than usual or if you want to change your usual diet.
- Are ill: continue taking your insulin. Your need for insulin may change.
- Go abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.
- Are pregnant, or planning a pregnancy or are breastfeeding please contact your doctor for advice.
- Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypoglycemic reaction coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypoglycemic reactions or if you find it hard to recognize hypoglycemia.

Other warnings you should know about:

Before you travel, check with your doctor or pharmacist on the availability of TRURAPI in other countries. If possible, bring enough TRURAPI with you on your trip.

Thiazolidinediones (class of oral antidiabetic drugs) used together with insulin may increase risk of edema (fluid retention/swelling of the lower extremities) and heart failure. Inform your doctor as soon as possible if you experience localised swelling (edema) or signs of heart failure such as unusual shortness of breath.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are on potassium lowering drugs or losing potassium (e.g. diarrhea).

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

TRURAPI may cause 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 take TRURAPI). Contact your healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TRURAPI:

Some medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Tell your doctor, Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia)

- 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 such as Aspirin® (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulfa antibiotics (used to treat infections)

If you take any of the medicines below, your blood sugar level may rise (hyperglycemia)

- 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 a hypoglycemia.

How to take TRURAPI:

You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. Follow their advice carefully. This leaflet is a general guide only.

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 TRURAPI exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much TRURAPI to use and when to use it.

- Check your insulin label each time you give your injection to make sure you are using the correct insulin;
- **Use the TRURAPI cartridge only with AllStar PRO and JuniorSTAR pens.**
- **Do not** make any dose changes unless your healthcare provider tells you to;
- TRURAPI is injected under your skin (subcutaneously). Inject it into the front of your thighs, upper arms, buttock or the front of your waist (abdomen);
- Injection sites within an injection area (abdomen, thigh, buttock or upper arm) must be rotated from one injection to the next. This will reduce the risk of skin shrinking or thickening or lumps at the site (see What are possible side effects from using TRURAPI);
- **Do not** use the exact same spot for each injection;
- **Do not** inject where the skin has pits, is thickened, or has lumps;
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin;
- **Do not** inject TRURAPI into your vein (intravenously);
- **Keep TRURAPI and all medicines out of the reach of children.**

TRURAPI is a clear solution and looks like some long-acting insulins. Always check for the name of the insulin on your carton and your TRURAPI cartridge label when you pick it up from the pharmacy to make sure it is the same as what your doctor recommended.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR AllStar PRO and JuniorSTAR, TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **OBTAIN AN ACCURATE DOSE.**
- ✗ The TRURAPI cartridge is for single patient use. Do not share it with anyone including other family members. Do not use on multiple patients.
- ✓ Always perform a safety test.
- ✓ Always carry a spare cartridge and spare needles in case they got lost or stop working.

As with all insulins, if patients are blind or have poor eyesight and cannot read the dose counter on the pen, they should get help from a person with good eyesight who is trained to use the insulin device.

Do not re-use the needle. A new sterile needle must be attached before each injection. Re-use of needles may increase the risk of blocked needles which may cause inaccurate dose delivery. Using a new sterile needle for each injection also minimizes the risk of contamination and infection.

Using the cartridge in any other injection pen not suitable for the TRURAPI cartridge could lead to a mistake in dosing and cause medical problems for you, such as a blood glucose level that is too low or too high.

- **JuniorSTAR delivers TRURAPI in 0.5 unit dose increments.**
- **AllStar PRO delivers TRURAPI in 1 unit dose increments.**

Although rare, technical problems with the cartridge can occur which may prevent correct dosing. They include: broken, cracked or damaged cartridges, air bubbles or foam, and blocked needles. If technical problems occur or are suspected, contact the call center, your physician, pharmacist or nurse.

Injection Procedure

Preparing the TRURAPI Cartridge for Insertion into the injection pen

1. To avoid medication errors, check the cartridge label of the insulin before each insertion.
2. Inspect the insulin cartridge. TRURAPI should be a clear and colourless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of the solution.
3. Make sure the insulin is at room temperature to minimize local irritation at the injection site.
4. Wash your hands.
5. Carefully follow the injection pen directions for loading the cartridge into the injection pen.

Injecting the Dose

1. Wash your hands.
2. Inspect the insulin. TRURAPI should be a clear and colourless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of solution.
3. It is not necessary to shake or rotate the cartridge inserted into the injection pen before use.
4. Remove the protective cap.
5. Follow the injection pen directions for attaching and changing the needle.
6. Check the cartridge inserted into the injection pen for air bubbles. If bubbles are present, remove them as instructed in the injection pen directions.
7. **Follow the injection pen directions for performing the Safety Test or Priming.**
8. Set the injection pen to the correct TRURAPI dose as instructed in the injection pen directions.
9. To avoid tissue damage, injection sites can be rotated so that the same site is not used more than approximately once a month.
10. Cleanse the skin with alcohol where the injection is to be made.
11. Pinch and hold the skin and insert the needle attached to the injection pen as instructed by your doctor or diabetes educator.
12. To inject TRURAPI, follow the directions for the injection pen.
13. Slowly count to 10 before removing the needle from the injection site and gently apply pressure for several seconds. **DO NOT RUB THE AREA.**
14. Remove the needle from the injection pen immediately after each injection as instructed in the directions for the injection pen. Dispose of the needle appropriately. Do not reuse the needle.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly. Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no deposition for long-term absorption.

Usual dose:

Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.,

Your usual TRURAPI dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your TRURAPI dose are illness, pregnancy, medication, exercise and travel.

Due to the faster onset of action, TRURAPI should be given close to a meal (start of the meal should be no more than 5-10 minutes after the injection). When necessary, TRURAPI can be given soon after a meal, instead of before the meal.

Overdose:

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual
4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin
6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease
7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

The warning signs of a hypoglycemia may come on suddenly and can include: 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; and difficulty concentrating.

Dietary Implications

If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

- If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon, you will need to eat glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or hospital emergency after an injection of glucagon: you need to find the reason for your hypoglycemia in order to avoid getting more.

If you think you, or a person you are caring for, have taken too much TRURAPI, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Causes of a hyperglycemia

You get a hyperglycemia if your blood sugar gets too high.

This might happen:

- If you forget to take insulin.
- If you repeatedly take less insulin than you need.
- If you eat more than usual.
- If you exercise less than usual.

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; a dry mouth and a fruity (acetone) smelling breath.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

If you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

What are possible side effects from using TRURAPI?

These are not all the possible side effects you may have when taking TRURAPI. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, TRURAPI can cause side effects, although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in "How to take TRURAPI?".

Less commonly reported side effects (1 to 10 users in 1000)

Signs of allergy

Hives and rash may occur.

Seek medical advice immediately

- If the above signs of allergy appear or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty breathing; have a rapid heartbeat; feel dizzy.

You may have a very rare serious allergic reaction to TRURAPI or one of its ingredients (called a generalized allergic reaction). See also the warning in “Do not use TRURAPI if”.

Vision problems

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

Skin changes at the injection site

If you inject yourself too often at the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (localized cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Changing the site with each injection reduces the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this site.

Swollen joints

When you start taking insulin, water retention may cause swelling around your ankles and other joints. This soon disappears.

Diabetic retinopathy (eye background changes)

If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

Rarely reported side effects (less than 1 user in 10,000)**Painful neuropathy (nerve related pain)**

If your blood glucose levels improve very fast you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Prior to first use, TRURAPI insulin cartridges should be stored in a refrigerator between 2° and 8°C.
- Do not freeze.
- Do not expose to excessive heat or sunlight.
- The pen and cartridge of TRURAPI that you are currently using should not be refrigerated but should be kept as cool as possible (15-30°C) and away from direct heat and light.
- Do not use TRURAPI if it has been frozen.
- Cartridges in use, or not refrigerated, should be discarded after 28 days, even if they still contain TRURAPI.

Inspection of Cartridge:

TRURAPI should be clear and colourless. DO NOT USE a cartridge of TRURAPI if it appears cloudy, thickened, or slightly coloured, or if solid particles are visible. A cartridge that is not clear and colourless or that is cracked or broken should be returned to the place of purchase for exchange.

If you notice anything unusual in the appearance or effect of your insulin, consult your healthcare professional

DO NOT USE A CARTRIDGE OF TRURAPI AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.

Dispose of used needles in a puncture-resistant container or as directed by your healthcare professional.

Dispose of used pens as instructed by your healthcare professional and without the needle attached. Keep out of reach and sight of children.

If you want more information about TRURAPI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-888-852-6887.

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This leaflet was prepared by sanofi-aventis Canada Inc.

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TRURAPI® SoloSTAR® (Pre-filled disposable pen) (pronounced) troo-RA-pee

Insulin aspart injection

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Contact your doctor, Diabetes Nurse Educator or pharmacist if you have any questions about this drug.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist. If you have trouble reading this, ask a family member or a friend for help.

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Serious Warnings and Precautions

- Hypoglycemia (low blood sugar) is the most common adverse effect of insulin, including TRURAPI.
- If hypoglycemia or hyperglycemic reactions are not treated they can result in the loss of consciousness, coma or death.
- Glucose monitoring is recommended for all patients with diabetes.
- Any change of insulin should be made cautiously and only under medical supervision. This may result in dosage adjustment.
- TRURAPI should be given immediately before a meal because of the fast onset of action (start of the meal should be not more than 5-10 minutes after injection). (see “How to take TRURAPI”)
- Never inject your insulin directly into a vein.
- TRURAPI should not be used if it is not water-clear and colourless.

What is TRURAPI used for?

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- You are allergic (hypersensitive) to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction. (see “What are possible side effects from TRURAPI?”)
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- The insulin has not been stored correctly or if it has been frozen. (see “How to store TRURAPI”)
- The insulin does not appear water-clear and colourless.

As a precautionary measure, you should carry an extra TRURAPI SoloSTAR pen and needles in case the pen does not work.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRURAPI. Talk about any health conditions or problems you may have, including if you:

- Have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
- Drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
- Have an infection, fever or have had an operation you may need more insulin than usual.
- Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
- Exercise more than usual or if you want to change your usual diet.
- Are ill: continue taking your insulin. Your need for insulin may change.
- Go abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.
- Are pregnant, or planning a pregnancy or are breastfeeding please contact your doctor for advice.
- Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypoglycemic reaction coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypoglycemic reactions or if you find it hard to recognize hypoglycemia.

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Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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Some medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Tell your doctor, Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia)

- 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 such as Aspirin® (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulfa antibiotics (used to treat infections)

If you take any of the medicines below, your blood sugar level may rise (hyperglycemia)

- 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)

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- 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 a hypoglycemia.

How to take TRURAPI:

You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. Follow their advice carefully. This leaflet is a general guide only.

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.

Read the detailed Instructions for Use that come with your TRURAPI® SoloSTAR® disposable prefilled pen. Use TRURAPI exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much TRURAPI to use and when to use it.

- Check your insulin label each time you give your injection to make sure you are using the correct insulin;
- TRURAPI comes in a SoloSTAR disposable prefilled pen that you must use to take your TRURAPI. The dose counter on your pen shows your dose of TRURAPI. Do not make any dose changes unless your healthcare provider tells you to;
- TRURAPI is injected under your skin (subcutaneously). Inject it into the front of your thighs, upper arms, buttock or the front of your waist (abdomen);
- Injection sites within an injection area (abdomen, thigh, buttock or upper arm) must be rotated from one injection to the next. This will reduce the risk of skin shrinking or thickening or lumps at the site (see What are possible side effects from using TRURAPI);
- **Do not** use the exact same spot for each injection;
- **Do not** inject where the skin has pits, is thickened, or has lumps;
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin;
- **Do not** inject TRURAPI into your vein (intravenously);
- **Keep TRURAPI and all medicines out of the reach of children.**

TRURAPI is a clear solution and looks like some long-acting insulins. Always check for the name of the insulin on your carton and your TRURAPI SoloSTAR pen label when you pick it up from the pharmacy to make sure it is the same as what your doctor recommended.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR TRURAPI SoloSTAR PEN TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **OBTAIN AN ACCURATE DOSE**
- ✗ The injection pen is for single patient use. Do not share it with anyone including other family members. Do not use on multiple patients.
- ✗ Never use your pen if it is damaged or if you are not sure that it is working properly.
- ✓ Always perform a safety test.
- ✓ Always carry a spare pen and spare needles in case they got lost or stop working.

The dose counter of the pen shows the number of units of TRURAPI to be injected.

As with all insulins, if patients are blind or have poor eyesight and cannot read the dose counter on the pen, they should get help from a person with good eyesight who is trained to use the insulin device.

Do not re-use the needle. A new sterile needle must be attached before each injection. Re-use of needles may increase the risk of blocked needles which may cause inaccurate dose delivery. Using a new sterile needle for each injection also minimizes the risk of contamination and infection.

Carefully read the “TRURAPI SoloSTAR pre-filled pen Instructions for Use” included in the package and use the pen as described. If you do not follow all of these instructions, you may get too much or too little insulin.

Injection Procedure

1. Take the new pen out of the fridge at least 1 hour before you inject. Make sure the insulin is at room temperature to minimize local irritation at the injection site; cold insulin is more painful to inject.
2. Check the name and expiration date on the label of your pen. To avoid medication errors between TRURAPI and other insulins, check the label on your TRURAPI SoloSTAR **pen to make sure you have the correct insulin before every injection. Never use your pen after the expiration date.**
3. **Check that the insulin is clear.** TRURAPI should be a clear and colourless solution with no visible particles. Do not use the pen if you notice anything unusual in the appearance of the solution.
4. **Wash your hands.**
5. **It is not necessary to shake or rotate the TRURAPI SoloSTAR pen before use.**
6. **Always attach a new needle.** Follow the TRURAPI SoloSTAR Instructions for Use for attaching and changing the needle.
7. **Pull off the protective cap and set it aside for later.**
8. **Do a safety test.** Always do a safety test before each injection to ensure your pen and needle are working correctly and to make sure that you get the correct insulin dose.
 - You may see air bubbles in the insulin – this is normal, they will not harm you.
9. **Select the correct dose.** Follow the steps included in your TRURAPI SoloSTAR Instructions for Use to ensure the correct dose of TRURAPI is selected.
 - Never select a dose or press the injection button without a needle attached – this may damage your pen.

10. **Choose a place to inject – upper arms, stomach, buttock or thighs.** There is no relevant difference in absorption of TRURAPI between your abdominal, thigh, buttock or upper arm subcutaneous injection areas.
 - Injection sites within an injection area (abdomen, thigh, buttock or upper arm) **MUST** be rotated from one injection to the next.
 11. **Cleanse the skin with alcohol where the injection is to be made.**
 12. **Push the needle into your skin as shown by your health provider.** Do not touch the injection button yet.
 13. **Place your thumb on the injection button – press all the way in and hold.** Do not press at an angle – your thumb could block the dose selector from turning.
 14. **Keep the injection button held in and when you see “0” in the dose window, slowly count to 10.** This will make sure you get your full dose. **DO NOT RUB THE AREA.**
 15. **Remove the needle immediately after each injection.** Follow the steps included in your TRURAPI SoloSTAR Instructions for Use – do not re-use the needle.
 - Always take care when handling needles – this is to prevent injury and cross-infection. Never put the inner needle cap back on.
 16. **Dispose of your needle appropriately.** Throw away the used needle in a puncture-resistant container or as instructed by your health provider or local authority.
 17. **Put the pen cap back on.** Do not put the pen back in the fridge.
- Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly. Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no deposition for long-term absorption.

Usual dose:

Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.,

Your usual TRURAPI dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your TRURAPI dose are illness, pregnancy, medication, exercise and travel.

Due to the faster onset of action, TRURAPI should be given close to a meal (start of the meal should be no more than 5-10 minutes after the injection). When necessary, TRURAPI can be given soon after a meal, instead of before the meal.

Overdose:

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual
4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin
6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease
7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

The warning signs of a hypoglycemia may come on suddenly and can include: 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; and difficulty concentrating.

Dietary Implications

If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

- If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon, you will need to eat glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or hospital emergency after an injection of glucagon: you need to find the reason for your hypoglycemia in order to avoid getting more.

If you think you, or a person you are caring for, have taken too much TRURAPI, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Causes of a hyperglycemia:

You get a hyperglycemia if your blood sugar gets too high.

This might happen:

- If you forget to take insulin.
- If you repeatedly take less insulin than you need.
- If you eat more than usual.
- If you exercise less than usual.

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; a dry mouth and a fruity (acetone) smelling breath.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

If you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

What are possible side effects from using TRURAPI?

These are not all the possible side effects you may have when taking TRURAPI. If you experience any side effects not listed here, tell your healthcare professional.

Like all medicines, TRURAPI can cause side effects, although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in "How to take TRURAPI?".

Less commonly reported side effects (1 to 10 users in 1000)

Signs of allergy

Hives and rash may occur.

Seek medical advice immediately

- If the above signs of allergy appear or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty breathing; have a rapid heartbeat; feel dizzy.

You may have a very rare serious allergic reaction to TRURAPI or one of its ingredients (called a generalized allergic reaction). See also the warning in "Do not use TRURAPI if".

Vision problems

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

Skin changes at the injection site

If you inject yourself too often at the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (localized cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Changing the site with each injection reduces the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this site.

Swollen joints

When you start taking insulin, water retention may cause swelling around your ankles and other joints. This soon disappears.

Diabetic retinopathy (eye background changes)

If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

Rarely reported side effects (less than 1 user in 10,000)

Painful neuropathy (nerve related pain)

If your blood glucose levels improve very fast you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Prior to first use, TRURAPI SoloSTAR should be stored in a refrigerator between 2° and 8°C.
- Do not freeze.
- Do not expose to excessive heat or sunlight.
- The TRURAPI SoloSTAR pen that you are currently using should not be refrigerated but should be kept as cool as possible (15-30°C) and away from direct heat and light.
- Do not use TRURAPI SoloSTAR if it has been frozen.
- Prefilled pens in use, or not refrigerated, should be discarded after 28 days, even if they still contain TRURAPI.

Inspection of the prefilled pen:

TRURAPI should be clear and colourless. DO NOT USE TRURAPI SoloSTAR if the solution appears cloudy, thickened, or slightly coloured, or if solid particles are visible. A prefilled pen cartridge that is not clear and colourless or that is cracked or broken should be returned to the place of purchase for exchange.

If you notice anything unusual in the appearance or effect of your insulin, consult your healthcare professional

DO NOT USE TRURAPI SoloSTAR AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.

Dispose of used needles in a puncture-resistant container or as directed by your healthcare professional.

Dispose of used pens as instructed by your healthcare professional and without the needle attached.

Keep out of reach and sight of children.

If you want more information about TRURAPI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-888-852-6887.

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This leaflet was prepared by sanofi-aventis Canada Inc.

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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

TRURAPI® Vials (pronounced) troo-RA-pee

Insulin aspart injection

Read this carefully before you start taking **TRURAPI** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRURAPI**.

Contact your doctor, Diabetes Nurse Educator or pharmacist if you have any questions about this drug.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist. If you have trouble reading this, ask a family member or a friend for help.

TRURAPI is a biosimilar biologic drug (biosimilar) to the reference biologic drug NovoRapid®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Hypoglycemia (low blood sugar) is the most common adverse effect of insulin, including TRURAPI.
- If hypoglycemia or hyperglycemic reactions are not treated they can result in the loss of consciousness, coma or death.
- Glucose monitoring is recommended for all patients with diabetes.
- Any change of insulin should be made cautiously and only under medical supervision. This may result in dosage adjustment.
- TRURAPI should be given immediately before a meal because of the fast onset of action (start of the meal should be not more than 5-10 minutes after injection). (see “How to take TRURAPI”)
- Never inject your insulin directly into a vein.
- TRURAPI should not be used if it is not water-clear and colourless.

What is TRURAPI used for?

- The treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia (high blood sugar).

How does TRURAPI work?

- TRURAPI is an insulin analogue used to treat diabetes.
- TRURAPI will start to lower your blood sugar 10-20 minutes after you take it, it has a maximum effect between 1 and 3 hours and the effects last for 3-5 hours. Due to this short action TRURAPI should normally be taken in combination with intermediate-acting or long-acting insulin preparations.
- Moreover TRURAPI can be used for continuous subcutaneous infusion in a pump system.

What are the ingredients in TRURAPI?

Medicinal ingredients: Insulin aspart

Non-medicinal ingredients: Hydrochloric acid, metacresol, phenol, polysorbate 20, sodium chloride, sodium hydroxide, water for injection, zinc chloride

TRURAPI comes in the following dosage forms:

Solution for Injection, 100 Units/mL

Do not use TRURAPI if:

- You feel a hypoglycemic reaction (low blood sugar) coming on. (see “What are possible side effects from TRURAPI?” for more about hypoglycemia).
- You are allergic (hypersensitive) to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction. (see “What are possible side effects from TRURAPI?”)
- If the protective cap is loose or missing. Each vial has a protective, aluminium cap with tear-off lid. If it is not in perfect condition when you get the vial, return the vial to your supplier.
- The insulin has not been stored correctly or if it has been frozen. (see “How to store TRURAPI”)
- The insulin does not appear water-clear and colourless.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TRURAPI. Talk about any health conditions or problems you may have, including if you:

- Have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
- Drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
- Have an infection, fever or have had an operation you may need more insulin than usual.
- Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
- Exercise more than usual or if you want to change your usual diet.
- Are ill: continue taking your insulin. Your need for insulin may change.
- Go abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.
- Are pregnant, or planning a pregnancy or are breastfeeding please contact your doctor for advice.
- Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypoglycemic reaction coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypoglycemic reactions or if you find it hard to recognize hypoglycemia.

Before you travel, check with your doctor or pharmacist on the availability of TRURAPI in other countries. If possible, bring enough TRURAPI with you on your trip.

Thiazolidinediones (class of oral antidiabetic drugs) used together with insulin may increase risk of edema (fluid retention/swelling of the lower extremities) and heart failure. Inform your doctor as soon as possible if you experience localised swelling (edema) or signs of heart failure such as unusual shortness of breath.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are on potassium lowering drugs or losing potassium (e.g. diarrhea).

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TRURAPI:

Some medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Tell your doctor, Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia)

- 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 such as Aspirin® (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulfa antibiotics (used to treat infections)

If you take any of the medicines below, your blood sugar level may rise (hyperglycemia)

- 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 a hypoglycemia.

How to take TRURAPI:

You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. Follow their advice carefully. This leaflet is a general guide only.

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.

TRURAPI 10 mL vial is also for continuous infusion in a pump system. TRURAPI may also be given intravenously by healthcare professionals under close supervision by a doctor.

Use TRURAPI exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much TRURAPI to use and when to use it.

- Check your insulin label each time you give your injection to make sure you are using the correct insulin;
- **Do not** make any dose changes unless your healthcare provider tells you to;
- TRURAPI is injected under your skin (subcutaneously);
- Injection sites within an injection area (abdomen, thigh, buttock or upper arm) must be rotated from one injection to the next;
- **Do not** use the exact same spot for each injection;
- **Do not** inject TRURAPI into your vein (intravenously);
- **Keep TRURAPI and all medicines out of the reach of children.**

TRURAPI is a clear solution and looks like some long-acting insulins. Always check for the name of the insulin on your carton and your TRURAPI vial label when you pick it up from the pharmacy to make sure it is the same as what your doctor recommended.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR TRURAPI VIAL, TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **OBTAIN AN ACCURATE DOSE.**
- ✗ The TRURAPI vial is for single patient use. Do not share it with anyone including other family members. Do not use on multiple patients.
- ✓ Always use a new needle for each injection to prevent contamination.
- ✓ Needles and syringes must not be shared.

As with all insulins, if patients are blind or have poor eyesight and cannot read the syringe graduations, they should get help from a person with good eyesight who is trained to use the insulin device.

Do not re-use the needle. A new sterile needle must be attached before each injection. Re-use of needles may increase the risk of blocked needles which may cause inaccurate dose delivery. Using a new sterile needle for each injection also minimizes the risk of contamination and infection.

Injection Procedure

Trurapi vial containing insulin aspart

- 1 Draw into the syringe the same amount of air as the dose of insulin you are going to inject. Inject the air into the vial.
- 2 Turn the vial and syringe upside down and draw the correct insulin dose into the syringe. Pull the needle out of the vial. Then expel the air from the syringe and check that the dose is correct.

How to inject Trurapi

- Inject the insulin under the skin. Use the injection technique advised by your doctor or nurse.
- Keep the needle under your skin for at least 6 seconds to make sure you have injected all the insulin.
- Discard the needle after each injection.

For use in an infusion pump system

Trurapi should never be mixed with any other insulin when used in a pump.

Follow the instructions and recommendations from your doctor regarding the use of Trurapi in a pump. Before use of Trurapi in the pump system, you must have received a comprehensive instruction in the use and information about any actions to be taken in case of illness, too high or too low blood sugar or failure of the pump system.

- Before inserting the needle, use soap and water to clean your hands and the skin where the needle is inserted to avoid any infection at the infusion site.
- When you fill a new reservoir, be certain not to leave large air bubbles in either the syringe or the tubing.
- Changing of the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.

To get the benefit of insulin infusion, and to detect possible malfunction of the insulin pump, it is recommended that you measure your blood sugar level regularly.

What to do in case of pump system failure

You should always have an alternative delivery method for your insulin available for injection under the skin in case of pump system failure.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly. Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no deposition for long-term absorption.

Usual dose:

Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.

Your usual TRURAPI dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your TRURAPI dose are illness, pregnancy, medication, exercise and travel.

Due to the faster onset of action, TRURAPI should be given close to a meal (start of the meal should be no more than 5-10 minutes after the injection). When necessary, TRURAPI can be given soon after a meal, instead of before the meal.

Overdose:

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual
4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin
6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease
7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

The warning signs of a hypoglycemia may come on suddenly and can include: 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; and difficulty concentrating.

Dietary Implications:

If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

- If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon, you will need to eat glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or hospital emergency after an injection of glucagon: you need to find the reason for your hypoglycemia in order to avoid getting more.

If you think you have taken too much TRURAPI, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Causes of a hyperglycemia:

You get a hyperglycemia if your blood sugar gets too high.

This might happen:

- If you forget to take insulin.
- If you repeatedly take less insulin than you need.
- If you eat more than usual.
- If you exercise less than usual.

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; a dry mouth and a fruity (acetone) smelling breath.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

If you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

What are possible side effects from using TRURAPI?

These are not all the possible side effects you may feel when taking TRURAPI. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, TRURAPI can cause side effects, although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in "How to take TRURAPI?".

Less commonly reported side effects (1 to 10 users in 1000)

Signs of allergy

Hives and rash may occur.

Seek medical advice immediately

- If the above signs of allergy appear or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty breathing; have a rapid heartbeat; feel dizzy.

You may have a very rare serious allergic reaction to TRURAPI or one of its ingredients (called a generalized allergic reaction). See also the warning in "Do not use TRURAPI if".

Vision problems

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

Changes at the injection site (lipodystrophy)

If you inject yourself too often at the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection reduces the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this site.

Swollen joints

When you start taking insulin, water retention may cause swelling around your ankles and other joints.

This soon disappears.

Diabetic retinopathy (eye background changes)

If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

Rarely reported side effects (less than 1 user in 10,000)

Painful neuropathy (nerve related pain)

If your blood glucose levels improve very fast you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Prior to first use, TRURAPI insulin vials should be stored in a refrigerator between 2° and 8°C.
- Do not freeze.
- Do not expose to excessive heat or sunlight.
- Do not use TRURAPI if it has been frozen.
- 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 freeze. Keep the vial in the outer carton in order to protect from light.

Inspection of Vial:

TRURAPI should be clear and colourless. DO NOT USE a vial of TRURAPI if it appears cloudy, thickened, or slightly coloured, or if solid particles are visible. A vial that is not clear and colourless or that is cracked or broken should be returned to the place of purchase for exchange.

If you notice anything unusual in the appearance or effect of your insulin, consult your healthcare professional

DO NOT USE A VIAL OF TRURAPI AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.

Dispose of used needles in a puncture-resistant container or as directed by your healthcare professional.

Keep out of reach and sight of children.

If you want more information about TRURAPI:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.sanofi.ca, or by calling 1-888-852-6887.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: July 20, 2022

TRURAPI® SOLOSTAR® - INSTRUCTIONS FOR USE

Read this first

Important information

- ✗ Never share your pen – it is only for you.
- ✗ Never use your pen if it is damaged or if you are not sure that it is working properly.
- ✗ **Never use a syringe to remove insulin from your pen.**
- ✓ Always perform a safety test.
- ✓ Always carry a spare pen and spare needles in case they got lost or stop working.

Learn to inject

- Talk with your healthcare provider about how to inject, before using your pen.
- This pen is not recommended for use by people who are blind or have visual impairments without the assistance of a person trained in the proper use of the product.
- Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little insulin.

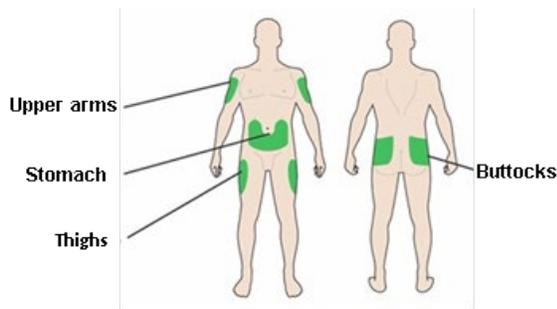
Need help?

If you have any questions about your pen or about diabetes, ask your healthcare provider, go to www.sanofi.ca or call sanofi-aventis at **1-888-852-6887**.

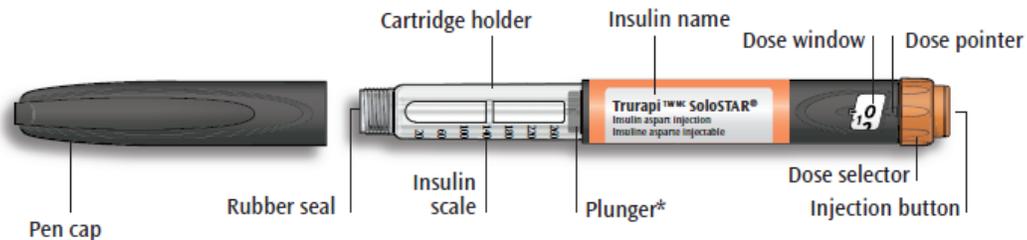
Extra items you will need:

- a new sterile needle (see STEP 2).
- an alcohol swab.
- a puncture resistant container for used needles and pens.

Places to inject



Get to know your pen



*You will not see the plunger until you have injected a few doses

STEP 1: Check your pen

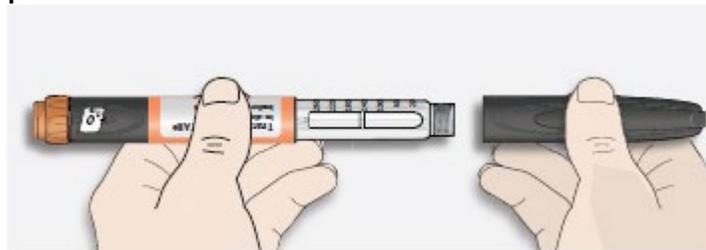
- ✓ Take a new pen out of the refrigerator at least 1 hour before you inject. Cold insulin is more painful to inject.

1A Check the name and expiration date on the label of your pen.

- Make sure you have the correct insulin.
- Never use your pen after the expiration date.

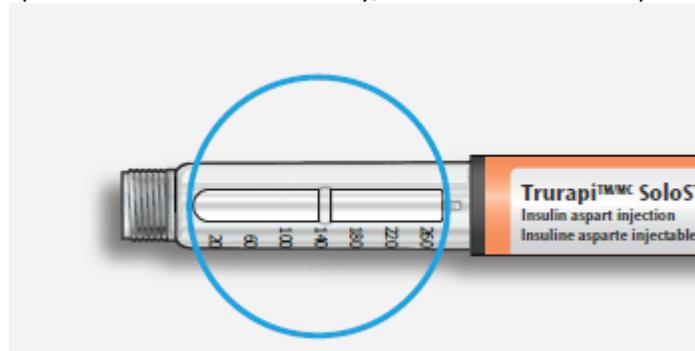


1B Pull off the pen cap.

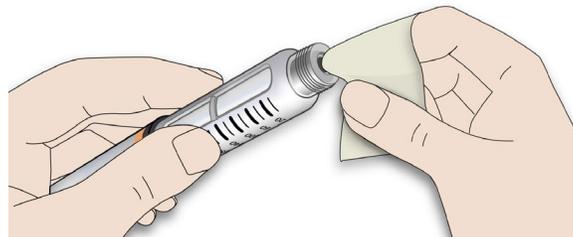


1C Check that the insulin is clear.

- Do not use the pen if the insulin looks cloudy, coloured or contains particles.



1D Wipe the rubber seal with an alcohol swab.



i If you have other injector pens

- Making sure you have the correct medicine is especially important if you have other injector pens.

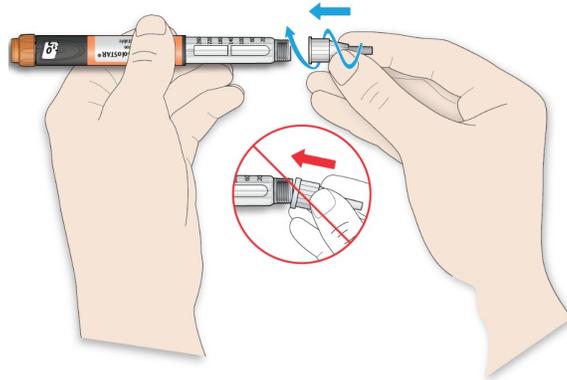
STEP 2: Attach a new needle

- ✓ Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
- ✓ Always use needles from Becton Dickinson (such as BD Ultra-Fine®), Ypsomed (such as Clickfine®) or Owen Mumford (such as Unifine® Pentips®)

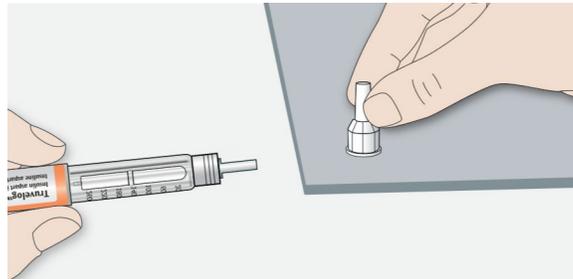
2A Take a new needle and peel off the protective seal.



2B Keep the needle straight and screw it onto the pen until fixed. Do not overtighten.



2C Pull off the outer needle cap. Keep this for later.



2D Pull off the inner needle cap and throw away.



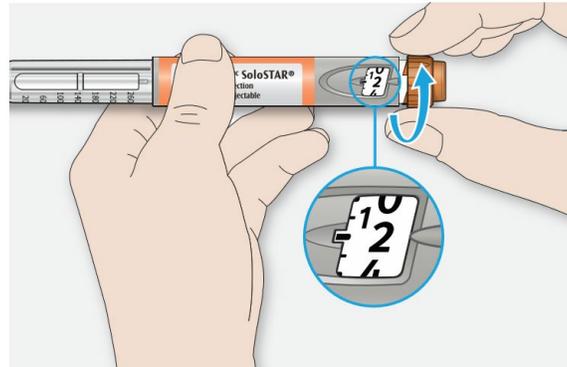
i Handling needles

- Take care when handling needles – this is to prevent needle injury and cross-infection.

STEP 3: Do a safety test

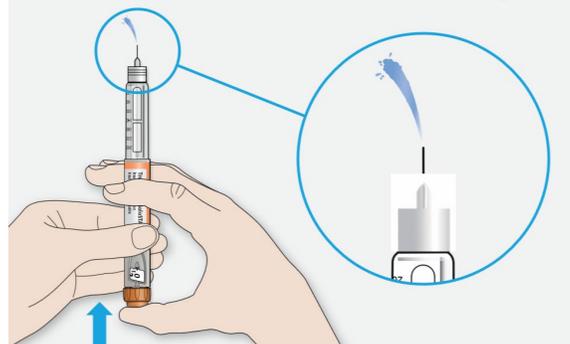
- ✓ Always do a safety test before each injection – this is to:
 - Check your pen and the needle are working properly.
 - Make sure that you get the correct insulin dose.
- ✓ You must perform safety tests before you use the pen until you see insulin coming out of the needle tip. If you see insulin coming out of the needle tip, the pen is ready to use. If you do not see insulin coming out before taking your dose, you could get an underdose or no insulin at all. This could cause high blood sugar.

3A Select 2 units by turning the dose selector until the dose pointer is at the 2 mark.



3B Press the injection button all the way in.

- When insulin comes out of the needle tip, your pen is working correctly.



3C Repeat this step if no insulin appears:

- **If you are using a new pen for the first time**, you may need to repeat this step **up to 3 times** before seeing insulin.
- **For all injections**, if no insulin comes out after the third time, the needle may be blocked. If this happens:
 - change the needle (see STEP 6 and STEP 2),
 - then repeat the safety test (STEP 3).
 - Do not use your pen if there is still no insulin coming out of the needle tip. Use a new pen.
 - Never use a syringe to remove insulin from your pen.
- **i If you see air bubbles**
 - You may see air bubbles in the insulin. This is normal, they will not harm you.

STEP 4: Select the dose

X Never select a dose or press the injection button without a needle attached. This may damage your pen.

4A Make sure a needle is attached and the dose is set to “0”.



4B Turn the dose selector until the dose pointer lines up with your dose.

- Always check the number in the dose window to make sure you dialed the correct dose.
- If you turn past your dose, you can turn back down.
- If there are not enough units left in your pen for your dose, the dose selector will stop at the number of units left.
- If you cannot select your full prescribed dose, use a new pen or inject the remaining units and use a new pen to complete your dose. If you use a new pen, perform a safety test (see STEP 3).



How to read the dose window

Even numbers are shown in line with the dose pointer:



20 units selected

Odd numbers are shown as a line between even numbers:



21 units selected

i Units of insulin in your pen

- Your pen contains a total of 300 units of insulin. You can select doses from 1 to 80 units in steps of 1 unit. Each pen contains more than one dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

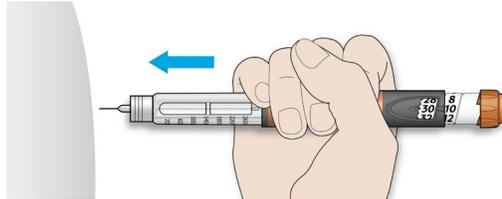
STEP 5: Inject your dose

X If you find it hard to press the injection button in, do not force it as this may break your pen. See the **i** section below for help.

5A Choose a place to inject as shown in the picture labelled “Places to inject”.

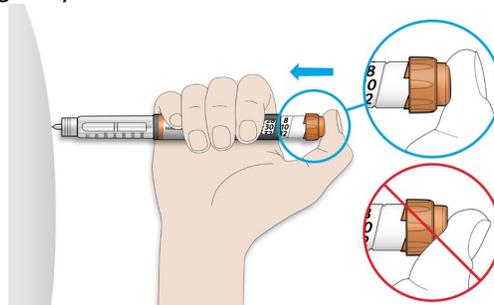
5B Push the needle into your skin as shown by your healthcare provider.

- Do not touch the injection button yet.



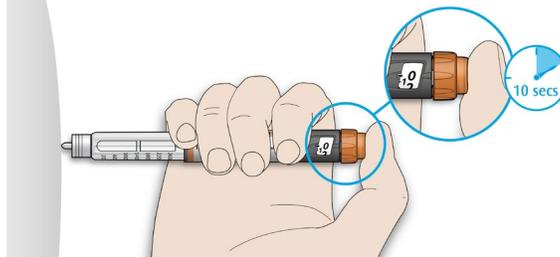
5C Place your thumb on the injection button. Then press all the way in and hold.

- Do not press at an angle – your thumb could block the dose selector from turning.



5D Keep the injection button held in and when you see "0" in the dose window, slowly count to 10.

- This will make sure you get your full dose.



5E After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.

i If you find it hard to press the button in:

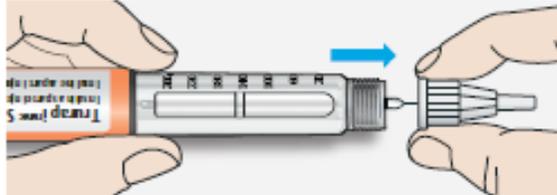
- Change the needle (see STEP 6 and STEP 2) then do a safety test (see STEP 3).
- If you still find it hard to press in, get a new pen.
- Never use a syringe to remove insulin from your pen.

STEP 6: Remove the needle

- ✓ Take care when handling needles – this is to prevent needle injury and cross-infection.
- ✗ Never put the inner needle cap back on.

**6A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back
Then push firmly on.**

- The needle can puncture the cap if it is recapped at an angle.

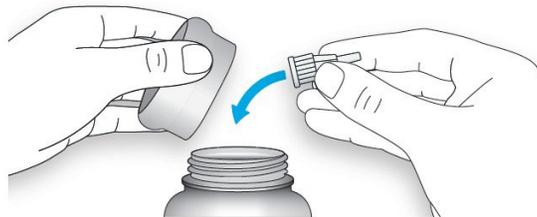


6B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.

- Try again if the needle does not come off the first time.

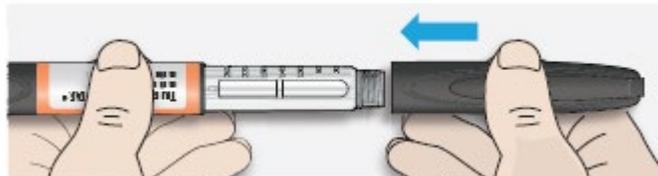


6C Throw away the used needle in a puncture resistant container, or as told by your healthcare provider or local authority.



6D Put the pen cap back on.

- Do not put the pen back in the refrigerator.



Use by

- Only use your pen for up to 4 weeks after its first use.

How to store your pen

Before first use

- Keep new pens in a refrigerator at **2°C to 8°C**.
- Do not freeze.

After first use

- Keep your pen at room temperature (15-30°C)
- Never put your pen back in the refrigerator.
- Never store your pen with the needle attached.
- Store your pen with the pen cap on.
- Keep your pen away from heat or light.
- **Keep this pen out of the sight and reach of children.**

How to care for your pen

Handle your pen with care

- Do not drop your pen or knock it against hard surfaces.
- If you think that your pen may be damaged, do not try to fix it, use a new one.

Protect your pen from dust and dirt

- You can clean the outside of your pen by wiping it with a clean, damp cloth (water only). Do not soak, wash or lubricate your pen – this may damage it.

Throwing your pen away

- Remove the needle before throwing your pen away.
- Throw away your used pen as told by your healthcare provider or local authority.

Last Revised: July 20, 2022

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