

TOUJEO

Insulin glargine 300 units/ml

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What Toujeo is used for

It is used to treat diabetes mellitus in adults, adolescents and children from the age of 6 years. Diabetes mellitus is an illness where your body does not make enough insulin to control your blood sugar.

How Toujeo works

Toujeo lowers your blood sugar steadily over a long period of time. It is used for once daily dosing.

You can change the time of your injection if you need to. This is because this medicine lowers your blood sugar over a long period of time.

Before you use Toujeo

-When you must not use it

If you are allergic to insulin glargine or any of the other ingredients of this medicine

-Before you start to use it

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Toujeo.

Follow closely the instructions for dose, monitoring (blood and urine tests), diet and physical activity (physical work and exercise) and injection technique, as discussed with your doctor.

Be especially aware of the following:

- Too low blood sugar (hypoglycaemia). If your blood sugar is too low, follow the guidance for hypoglycaemia
- If you switch from another type, brand or manufacturer of insulin your insulin dose may need to be changed.
- Pioglitazone. See "Pioglitazone used together with insulin".
- Ensure to use the right insulin. Medication errors due to mix-up between insulins, particularly between long-acting insulins and rapid-acting insulins have been reported. You must always check the insulin label before

each injection to avoid mix-ups between Toujeo and other insulins.

- Never use a syringe to remove Toujeo from your SoloStar pre-filled pen. This is to avoid dosing errors and potential overdose which may lead to low blood sugar.

- If you are blind or have poor eyesight, do not use the pre-filled pen without help. This is because you will not be able to read the dose window on the pen. Get help from a person with good eyesight who is trained in using the pen.

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 Toujeo). 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.

Illnesses and injuries

In the following situations, the management of your diabetes may require extra care (for example, blood and urine tests):

- If you are ill or have a major injury. Your blood sugar level may increase (hyperglycaemia).
 - If you are not eating enough. Your blood sugar level may become too low (hypoglycaemia).
- In most cases you will talk to a doctor. Contact a doctor as soon as you feel ill or get an injury.

If you have "Type 1" diabetes and you have an illness or injury:

- Do not stop your insulin
 - Keep eating enough carbohydrates.
- Always tell people who are caring or treating you, that you have diabetes.

Insulin treatment can cause the body to produce antibodies to insulin (substances that act against insulin). However, only very rarely, this will require a change to your insulin dose.

Travel

Talk to your doctor before travelling.

- If your type of insulin is available in the country you are visiting.

- How to arrange the supply of insulin, needles and other items.

- How to correctly store your insulin while travelling.

- The time you eat meals and use your insulin.

- The possible effects of changing to different time zones.

- Any health risks in the countries you will visit.

- What you should do in an emergency situation if you feel unwell or become ill.

Children and adolescents

This medicine should not be used in children under 6 years of age. This is because there is no experience with Toujeo in this age group.

-Taking other medicines

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

Some medicines can change your blood sugar level. This may mean your insulin dose has to change.

So, before taking a medicine ask your doctor if it will affect your blood sugar and what action, if any, you need to take. You also need to be careful when you stop taking a medicine.

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

- Any other medicine to treat diabetes.
- Disopyramide – for some heart problems.
- Fluoxetine – for depression.
- Sulfonamide antibiotics.
- Fibrates – for lowering high levels of blood fats.
- Monoamine oxidase inhibitors (MAOIs) – for depression.
- Angiotensin converting enzyme (ACE) inhibitors – for heart problems or high blood pressure.
- Medicines to relieve pain and lower fever, such as pentoxifylline, propoxyphene and salicylates (such as acetylsalicylic acid).
- Pentamidine – for some infections caused by parasites. This may cause too low blood sugar which is sometimes followed by too high blood sugar.

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

- Corticosteroids such as cortisone for inflammation.

- Danazol – for endometriosis.
- Diazoxide – for high blood pressure.
- Protease inhibitors- for HIV.
- Diuretics – for high blood pressure or fluid retention.
- Glucagon – for very low blood sugar.
- Isoniazid – for tuberculosis.
- Somatropin – a growth hormone.
- Thyroid hormones – for thyroid gland problems.
- Oestrogens and progestogens – such as in the contraceptive pill for birth control.
- Clozapine, olanzapine and phenothiazine derivatives – for mental health problems.
- Sympathomimetic medicines such as epinephrine (adrenaline), salbutamol and terbutaline – for asthma.

Your blood sugar level may either rise or fall if you take:

- Beta-blockers or clonidine – for high blood pressure.
- Lithium salts – for mental health problems.

Beta-blockers

Beta-blockers like other “Sympatholytic medicines” (such as clonidine, guanethidine, reserpine – for high blood pressure) may make it harder to recognise warning signs of your blood sugar being too low (hypoglycaemia). It can even hide or stop the first signs that your blood sugar is too low.

Pioglitazone used together with insulin

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

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before using Toujeo.

Toujeo with alcohol

Your blood sugar level may either rise or fall if you drink alcohol. You should check your blood sugar level more than usual.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Your insulin dose may need to be

changed during pregnancy and after giving birth. For the health of your baby, it is particularly important to carefully control your diabetes and to prevent hypoglycaemia.

If you are breast-feeding, talk to your doctor, as your insulin doses and your diet might need to be changed.

Important information about some of the ingredients of Toujeo

This medicine contains less than 1 mmol (23 mg) sodium per dose. This means it is essentially ‘sodium-free’.

How to use Toujeo

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Although Toujeo contains the same active substance as insulin glargine 100 units/ml, these medicines are not interchangeable. The switch from one insulin therapy to another requires medical prescription, medical supervision and blood glucose monitoring. Consult your doctor for further information.

-How much to use

The Toujeo SoloStar pre-filled pen can provide a dose of 1 to 80 units in one injection, in steps of 1 unit.

The dose window of the SoloStar pen shows the number of units of Toujeo to be injected. Do not make any dose recalculation.

Based on your lifestyle, your blood sugar tests and your previous insulin use, your doctor will tell you:

- How much Toujeo you need each day and at what time.
- When to check your blood sugar level and if you need to carry out urine tests.
- When you may need a higher or lower dose.

Toujeo is a long-acting insulin. Your doctor may tell you to use it with a short-acting insulin, or with other medicines for high blood sugar.

If you use more than one insulin always ensure you use the right insulin by checking the insulin label before each injection. Medication errors due to mix-up between insulins, particularly between long-acting insulins and rapid-acting insulins have been reported. The strength “300” is highlighted on the label of your Toujeo SoloStar pre-filled pen. Ask your doctor or pharmacist if you are not sure.

Many factors may affect your blood sugar level. You should know these

factors so that you can take the right action if your blood sugar level changes and help stop it becoming too high or too low.

-When to use it

Flexibility in time of administration

- Use Toujeo once a day, preferably at the same time every day.
- When needed, you can inject it up to 3 hours before or after the usual time that you use it.

Use in elderly patients (65 years and over)

If you are 65 years or older, talk to your doctor as you may need a lower dose.

If you have kidney or liver problems

If you have kidney or liver problems, talk to your doctor as you may need a lower dose.

Before injecting Toujeo

- Read the instructions for use that come with this package leaflet.
- If you do not follow all of these instructions, you may get too much or too little insulin.

How to inject

- Toujeo is injected under the skin (subcutaneous use or “SC”).
- Inject it into the front of your thighs, upper arms or the front of your waist (abdomen).
- Change the place within the area you inject each day. This will reduce the risk of skin shrinking or thickening.

To prevent the possible transmission of disease, insulin pens should never be used for more than one person, even when the needle is changed.

Always attach a new sterile needle before each injection. Never re-use needles. If you re-use a needle this increases the risk of it becoming blocked and of you getting too much or too little insulin.

Throw away the used needle in a puncture resistant container, or as told by your pharmacist or local authority.

-How long to use it

If you stop using Toujeo

Do not stop using this medicine without talking to your doctor. If you do, it could lead to very high blood sugar and a build-up of acid in the blood (ketoacidosis).

-If you forget to use it

When needed, Toujeo can be injected up

to 3 hours before or after the time you usually inject it.

If you have missed a dose of Toujeo or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia):

- Do not inject a double dose to make up for a forgotten dose.
- Check your blood sugar and then inject your next dose at the usual time.

-If you use too much (overdose)

If you have injected too much of this medicine, your blood sugar level may become too low. Check your blood sugar and eat more food to prevent your blood sugar getting too low.

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

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Toujeo.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not use Toujeo

- In a vein. This will change the way it works and may cause your blood sugar to become too low.
- In an insulin infusion pump.
- If there are particles in the insulin. The solution should be clear, colourless and water-like.
- Never use a syringe to remove Toujeo from your SoloStar pen or severe overdose can result.
- If the SoloStar pen is damaged, has not been stored correctly, if you are not sure that it is working properly or you notice that your blood sugar control is unexpectedly getting worse:
 - Throw the pen away and use a new one.
 - Talk to your doctor, pharmacist or nurse if you think you have problem with your pen.

-Things to be careful of

Driving and using machines

Having too low or too high blood sugar or sight problems can affect your ability to drive and use tools or machines. Your concentration may be affected. This could be dangerous to yourself and others.

Ask your doctor whether you can drive if:

- Your blood sugar is often too low.
- You find it hard to recognise when your blood sugar is too low.

Side effects

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

If you notice signs of your blood sugar being too low (hypoglycaemia), take action to increase your blood sugar level straight away.

Hypoglycaemia can be very serious and is very common with insulin treatment (may affect more than 1 in 10 people).

- Low blood sugar means that there is not enough sugar in your blood.
- If your blood sugar falls too low, you may pass out (become unconscious).
- Serious low blood sugar may cause brain damage and may be life-threatening.

Severe allergic reactions (rare, may affect up to 1 in 1,000 people). The signs may include rash and itching all over the body, swelling of skin or mouth, shortness of breath, feeling faint (a fall in blood pressure) with fast heartbeat and sweating. Severe allergic reactions may become life-threatening. Tell a doctor straight away if you notice signs of a severe allergic reaction.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Skin changes at the injection site: If you inject insulin too often at the same place, the skin may either shrink (lipatrophy) (*may affect up to 1 in 100 people*) or thicken (lipohypertrophy) (*may affect up to 1 in 10 people*). Lumps under the skin may also be caused by build-up of a protein called amyloid. Frequency 'not known': Changes at the injection site (Cutaneous amyloidosis). The insulin may not work very well if you inject into lumpy areas. Change the injection site with each injection to help prevent these skin changes.

Common: may affect up to 1 in 10 people

- Skin and allergic reactions at the injection site: The signs may include reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. This can spread around the injection site. Most minor reactions

to insulins usually disappear in a few days to a few weeks.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Toujeo

-Storage

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 carton and on the label of the pen after "EXP". The expiry date refers to the last day of that month.

Before first use

Store in a refrigerator (2°C-8°C). Do not freeze or place next to the freezer compartment or a freezer pack. Keep the pen in the outer carton in order to protect from light.

After first use or if carried as a spare

Do not store the pen in a refrigerator. The pen may be stored for a maximum of 6 weeks below 30°C and away from direct heat or direct light. Discard the pen after this time period. Do not leave your insulin in a car on an exceptionally warm or cold day. Always keep the cap on the pen when you are not using it in order to protect from light.

-Disposal

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

Product description

-What it looks like

Toujeo is a clear and colourless solution. Each pen contains 1.5 ml of solution for injection (equivalent to 450 units). Packs of 1, 3 and 5 pre-filled pens. Not all pack sizes may be marketed.

-Ingredients

- Active ingredients: insulin glargine. Each ml of the solution contains 300 units of insulin glargine (equivalent to 10.91 mg). Each pen contains 1.5 ml of solution for injection, equivalent to 450 units.
- Inactive ingredients: zinc chloride, metacresol, glycerol, water for injections, and sodium hydroxide and hydrochloric acid (for pH adjustment).

-MAL Number

MAL16075050AZ

Manufacturer

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Product Registration Holder

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Date of revision

28/04/2022 (EU SmPC 10 Aug 2020).

Serial Number:

NPRA(R3/01)25042022/0187