

Toujeo® SoloStar®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Toujeo SoloStar?

Toujeo SoloStar contains the active ingredient insulin glargine 300 units/mL. Toujeo SoloStar is used to reduce high blood sugar (hyperglycaemia) in patients 6 years of age and older, who have diabetes.

For more information, see Section [1. Why am I using Toujeo SoloStar?](#) in the full CMI.

2. What should I know before I use Toujeo SoloStar?

Do not use if you have ever had an allergic reaction to insulin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you:

- **have diabetic ketoacidosis (often caused by high blood sugar levels)**

- **have any other medical conditions, including kidney or liver problems**
- **take any other medicines**
- **are pregnant, or plan to become pregnant, or are breastfeeding.**

For more information, see Section [2. What should I know before I use Toujeo SoloStar?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Toujeo SoloStar and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Toujeo SoloStar?

- Toujeo SoloStar should be injected under the skin. Your doctor will tell you when and how much Toujeo SoloStar you need to use each day.
- Your doctor may change your dose, depending on your blood sugar levels.
- Use Toujeo SoloStar until your doctor tells you to stop. Too much or too little insulin can cause serious effects.
- Toujeo SoloStar should be used once a day, at the same time every day.

More instructions can be found in Section [4. How do I use Toujeo SoloStar?](#) in the full CMI.

5. What should I know while using Toujeo SoloStar?

Things you should do	<ul style="list-style-type: none">● It is very important that you manage your diabetes carefully. Measure your blood sugar levels regularly.● Tell your doctor if you often have low blood sugar levels or ever lose consciousness after using Toujeo SoloStar.● Always carry sugary food or drink with you in case you start to have any symptoms of low blood sugar.● Remind any doctor, dentist, diabetes educator or pharmacist you visit that you are using Toujeo SoloStar.
Drinking alcohol	<ul style="list-style-type: none">● Tell your doctor if you drink alcohol. Drinking alcohol may mask the symptoms of low blood sugar.

Looking after your medicine

- Keep unopened Toujeo SoloStar pre-filled pens in the fridge between 2-8°C. Do not freeze.
- Before using a new pen, take it out of the fridge and let it come to room temperature for 1-2 hours.
- After you have started using a pen, do not put it back in the fridge. Keep it at room temperature below 30°C, away from direct heat and light.
- **Discard any pen you have started using or any spare pen taken out of the fridge within 28 days.**

For more information, see Section [5. What should I know while using Toujeo SoloStar?](#) in the full CMI.

6. Are there any side effects?

Serious side effects may include low blood sugar (hypoglycaemia or 'hypo') or an allergic reaction. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Toujeo[®] SoloStar[®] (too-jay-oh)

Active ingredient: *insulin glargine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Toujeo SoloStar. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Toujeo SoloStar.**

Where to find information in this leaflet:

- [1. Why am I using Toujeo SoloStar?](#)
- [2. What should I know before I use Toujeo SoloStar?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Toujeo SoloStar?](#)
- [5. What should I know while using Toujeo SoloStar?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Toujeo SoloStar?

Toujeo SoloStar contains the active ingredient insulin glargine. Insulin glargine is a modified insulin that is a substitute for the insulin produced by your pancreas.

Toujeo SoloStar contains 3 times more insulin in 1 mL than standard insulin, which contains 100 unit/mL.

Toujeo SoloStar is used to reduce high blood sugar (hyperglycaemia) in patients 6 years of age and older, with diabetes mellitus (commonly known as 'diabetes').

Toujeo SoloStar is a long-acting insulin. Your doctor may tell you to use a meal time insulin or oral anti-diabetic medication in combination with Toujeo SoloStar.

2. What should I know before I use Toujeo SoloStar?

Warnings

Do not use Toujeo SoloStar if:

- You have ever had an allergic reaction to a medicine containing insulin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have diabetic ketoacidosis (often caused by high blood sugar levels),

Tell our doctor if you:

- have any other medical conditions, including any kidney problems or liver problems.
- take any medicines for any other condition
- drink alcohol
- do not eat regular meals

- do a lot of exercise
- are ill or are feeling unwell.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Pregnancy may make managing your diabetes more difficult.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Toujeo SoloStar and affect how it works.

Medicines that may increase the blood sugar lowering effect of Toujeo SoloStar include:

- oral anti-diabetic medicines for type 2 diabetes
- some blood pressure, blood flow, cholesterol and heart medications
- some medications for pain and inflammation

- some antidepressants
- certain antibiotics that contain sulfur

Medicines that may reduce the blood sugar lowering effect of Toujeo SoloStar include:

- hormonal therapies, such as corticosteroids, glucagon
- oral contraceptives and gynaecological medications
- some fluid and glaucoma medications
- some medicines to treat tuberculosis and HIV/AIDS
- some psychiatric medications
- adrenaline and asthma medications such as salbutamol, terbutaline

Medicines that may mask the symptoms of low blood sugar (hypoglycaemia or 'hypo') include:

- certain heart medications, especially beta-blockers.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Toujeo SoloStar.

4. How do I use Toujeo SoloStar?

How much to use

- Your doctor will tell you how much Toujeo SoloStar you need to use each day.
- Follow the instructions provided and use Toujeo SoloStar until your doctor tells you to stop.
- Your doctor may change your dose, depending on your blood sugar levels

When to use Toujeo SoloStar

- Your doctor will tell you what time of day to use Toujeo SoloStar.
- Toujeo SoloStar should be used once a day, at the same time every day.

How to inject Toujeo SoloStar

Toujeo SoloStar should be injected under the skin, being careful not to inject it into a muscle or vein.

Inject Toujeo SoloStar into 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 or lumps at the site (see "Side effects").

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.

- Always check the label on your Toujeo SoloStar pre-filled pen before using it to make sure you have the correct insulin.
- Make sure that 'U300' is highlighted in honey gold colour on the label of your Toujeo SoloStar pre-filled pen.
- **Use a new needle each time you inject Toujeo SoloStar.**

This helps to avoid under-dosing or over-dosing due to blockages.

Toujeo SoloStar should be injected under the skin. Inject the full dose of Toujeo SoloStar by pushing the plunger as far as it will go. Your doctor or diabetes educator will have shown you how to use Toujeo SoloStar.

- **Do not try to withdraw Toujeo SoloStar from the cartridge of the pre-filled pen into a syringe.**

Use a different injection site for each injection so that the same site is not used more often than once a month. This will reduce the chance of local skin reactions developing.

If you develop 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. 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.

If you forget to use Toujeo SoloStar

Toujeo SoloStar is a long-acting insulin and should be used regularly at the same time each day. If you forget to take your insulin dose at the usual time, your blood sugar levels may become high (hyperglycaemia).

If you miss a dose and are not sure what to do, contact your doctor or pharmacist for specific advice.

Do not take a double dose of insulin.

If you use too much Toujeo SoloStar

If you think that you have used too much Toujeo SoloStar, your blood sugar level may become too low (hypoglycaemia or 'hypo'). You may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26** in Australia; **0800 POISON** or **0800 764 766** in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Toujeo SoloStar?

Things you should do

Measure your blood sugar level regularly. It is important that you manage your diabetes carefully. Too much or too little insulin can cause serious side effects.

Call your doctor straight away if you:

- often have low blood sugar levels
- ever lose consciousness after using Toujeo SoloStar.

Your doctor may need to adjust your dose of Toujeo SoloStar or of other medicines you are taking.

Remind any doctor, dentist, diabetes educator or pharmacist you visit that you are using Toujeo SoloStar.

Tell your relatives, carers, friends and close workmates that you have diabetes.

Low blood sugar levels and what to do

You may experience low blood sugar if your levels are reduced too much. Early symptoms of mild to moderate low blood sugar can come on suddenly and may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heartbeat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea.

Always carry some sugary food or drink with you.

If you start to get any symptoms of low blood sugar:

- **have some sugary food or drink, and**
- **follow up with extra carbohydrates once the initial symptoms have stopped.**

Make sure people close to you know how to recognise the symptoms of low blood sugar, and that they need to get you medical help immediately if you become unconscious.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Toujeo SoloStar affects you. Be careful not to let your blood sugar levels fall too low.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- Keep unopened Toujeo SoloStar pre-filled pens in the fridge between 2-8°C. Do not freeze.
- Before using a new pen, take it out of the fridge and let it come to room temperature for 1 to 2 hours.
- After you have started using a pen, do not put it back in the fridge. Keep it at room temperature below 30°C, away from direct heat and light.

Keep it where young children cannot reach it.

When to discard your medicine

Discard any pre-filled pen you have started using or any spare pen taken out of the fridge, after 28 days.

Discard any pens that are frozen or have been frozen.

Getting rid of any unwanted medicine

Your doctor, pharmacist or diabetes educator will show you how to safely dispose of your needles and pre-filled pens once they are empty.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Low blood sugar-related:</p> <ul style="list-style-type: none"> • hypoglycaemia (mild to moderate) – a list of early symptoms of ‘hypo’ can be found in Section 5. What should I know while using Toujeo SoloStar? <p>Injection site-related:</p> <ul style="list-style-type: none"> • redness, swelling or itching at the injection site • hollowing or thickening of the skin around the injection site 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Skin changes at the injection site:

If you inject insulin too often at the same place, the fatty tissue may either 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. Change the injection site with each injection to help prevent these skin changes.

Serious side effects

Serious side effects	What to do
<p>Low blood sugar related:</p> <p>More severe symptoms of hypoglycaemia, including:</p> <ul style="list-style-type: none">• disorientation• seizures, fits or convulsions• loss of consciousness <p>Signs of a serious allergic reaction, including:</p> <ul style="list-style-type: none">• skin rashes over a large part of the body• shortness of breath, wheezing• swelling of the face, lips or tongue• fast pulse• sweating	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Always speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects as follows:

For Australia: Therapeutic Goods Administration online at: www.tga.gov.au/reporting-problems.

New Zealand: Medsafe online at: <https://www.medsafe.govt.nz/safety/report-a-problem.asp>

By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What Toujeo SoloStar contains

Active ingredient (main ingredient)	Insulin glargine (300 units/ mL)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● meta-cresol● glycerol● zinc chloride● hydrochloric acid

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|--|--|
| | <ul style="list-style-type: none">• sodium hydroxide• water for injection |
|--|--|

Do not take this medicine if you are allergic to any of these ingredients.

You can get more information about diabetes and insulin from Diabetes Australia:

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au

Diabetes NZ:

- freecall helpline: 0800 369 636
- www.diabetes.org.nz

What Toujeo SoloStar looks like

Toujeo SoloStar is a pre-filled disposable pen containing a 1.5 mL cartridge of Toujeo SoloStar.

AUST R [223457](#)

Who distributes Toujeo SoloStar

Toujeo SoloStar is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall No: 1800 818 806

Toujeo SoloStar is supplied in New Zealand by:

sanofi-aventis new zealand limited

Level 8

56 Cawley Street

Ellerslie, Auckland

Freecall No: 0800 283 684

Full Product Information is available from sanofi-aventis australia pty ltd at http://products.sanofi.com.au/aus_pi_toujeo.pdf

or by calling 1800 818 806

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