

TOUJEO[®] MAX SOLOSTAR[®]

(*tou-jeo*)

insulin glargine (in-sue-lin glar-jeen)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Toujeo Max SoloStar.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Toujeo Max SoloStar against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Toujeo Max SoloStar is used for

Toujeo Max SoloStar contains the active substance insulin glargine.

Toujeo Max SoloStar is used to reduce high blood sugar (glucose) levels in adults with diabetes mellitus.

Toujeo Max SoloStar is a modified insulin that is very similar to human insulin. It is a substitute for the insulin produced by the pancreas.

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

Toujeo Max SoloStar is not addictive.

Ask your doctor if you have any questions about why Toujeo Max SoloStar has been prescribed for you.

Before you use Toujeo Max SoloStar

When you must not use Toujeo Max SoloStar

Do not use Toujeo Max SoloStar if:

- You have diabetic ketoacidosis (often caused by high blood glucose levels)
- you are allergic to any medicine containing insulin or any of the ingredients contained in Toujeo Max SoloStar listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- **If you are experiencing low blood sugar levels (hypoglycaemia - a "hypo").**

If you have a lot of hypos discuss appropriate treatment with your doctor.

- **After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If you use Toujeo Max SoloStar after the expiry date has passed, it may not work as well. If it has expired or if the packaging is damaged, return it to your pharmacist for disposal.

- **If the product appears cloudy, discoloured or contains particles, or if the injection pen appears damaged.**

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not give Toujeo Max SoloStar to a child or adolescent.

Toujeo Max SoloStar has not been studied for use in children or adolescents under 18 years old.

Before you start to use Toujeo Max SoloStar

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems

Tell your doctor if you are pregnant or plan to become pregnant.

Pregnancy may make managing your diabetes more difficult.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Tell your doctor if:

- you drink alcohol
- you do not eat regular meals
- you do a lot of exercise
- you are ill or feeling unwell

Alcohol, diet, exercise and your general health all affect the control of your diabetes.

If you have not told your doctor about any of the above, tell them before you start using Toujeo Max SoloStar.

Taking other medicines

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

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

- oral antidiabetic medicines that are used to treat type 2 diabetes
- blood pressure, blood flow, cholesterol and heart medications
- medications for pain and inflammation
- some antidepressants
- sulfonamide antibiotics

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

- corticosteroids, glucagon and other hormonal therapies
- oral contraceptives and gynaecological medications
- fluid and glaucoma medications
- tuberculosis and HIV/AIDS treatments
- some psychiatric medications

- adrenaline and asthma medications such as salbutamol, terbutaline

Certain heart medications, especially beta-blockers, may mask the symptoms of hypoglycaemia.

Your doctor and pharmacist have a full list of medicines with which you must be careful or avoid while using Toujeo Max SoloStar. Please check with your doctor or pharmacist before starting any new medicines or over-the-counter products.

How to use Toujeo Max SoloStar

Toujeo Max SoloStar is a clear solution that does not require shaking before use.

Your doctor, pharmacist or diabetes educator will have shown you how to use Toujeo Max SoloStar.

Read carefully the instructions for use for Toujeo Max SoloStar provided in the carton. You must use the pen as described in these Instructions for Use.

Do not dilute Toujeo Max SoloStar.

Do not mix Toujeo Max SoloStar with any other insulin or solution.

Toujeo Max SoloStar and insulin glargine 100 units/mL (Lantus) injection both contain the same active ingredient, insulin glargine, and therefore should not be used together.

When transitioning from other insulin to Toujeo Max SoloStar or from Toujeo Max SoloStar to other insulin pens. A program of close blood sugar monitoring under medical supervision is recommended during the change and in the initial weeks thereafter.

Do not inject Toujeo Max SoloStar into a vein.

Toujeo Max SoloStar is intended for injection under the skin.

Any change in this medicine should be made cautiously and only under medical supervision.

If you do not understand the instructions, ask your doctor, pharmacist or diabetes educator for help.

How much to use

The Toujeo max SoloStar pre-filled pen can provide a dose of 2 to 160 units per injection, in steps of 2 units. The pen is recommended for patient who need at least 20 units of insulin per day.

The dose window of the DoubleStar pen shows the number of units of Toujeo to be injected. Do not make any dose re-calculation.

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.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use Toujeo Max SoloStar

Your doctor will tell you when to use Toujeo Max SoloStar.

Toujeo Max SoloStar should be used once a day, at the same time every day.

How to use Toujeo Max SoloStar

ALWAYS CHECK YOUR TOUJEO MAX SOLOSTAR INJECTION PEN

Do not use Toujeo Max SoloStar if it is no longer clear and colourless or if it contains particles.

Make sure you are using the correct injection pen

Always check the insulin label before each injection to make sure you are using the right insulin. The “U300” is highlighted in honey gold on the label.

Keep the injection pen at room temperature for 1 or 2 hours before use. Cold insulin is more painful to inject.

Toujeo Max SoloStar disposable pens are pre-filled and ready to use. Once all the insulin is used you cannot replace the cartridge.

Carefully follow the instructions provided with the Toujeo Max SoloStar pens for attaching a needle, performing a safety test and administering the insulin injection.

Never use an injection pen if it is damaged or you are not sure that it is working properly. Use a new pen.

Always use needles from Beckton Dickinson (BD), Ypsomed or Owen Mumford.

INJECTING A DOSE

Use a new needle every time you inject – Re-use of needles increases the risks of blocked needles which may cause underdosing and overdosing.

Toujeo Max SoloStar must not be withdrawn from the cartridge of the pre-filled pen into a syringe.

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

Choose a site for injection.

Inject Toujeo Max SoloStar into the abdomen, thighs or upper arms.

1. With one hand, stabilise the skin by spreading it or pinching up a

large area, as recommended by your healthcare professional.

2. Insert the needle into the skin as recommended by your healthcare professional.
3. Inject the full dose of Toujeo Max SoloStar by pushing the plunger as far as it will go.
4. Slowly count to 5 before removing the needle from the skin.

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.

AFTER INJECTING

Using the outer needle cap, unscrew the needle and dispose of it safely into a sharps container.

Do not share needles. Do not reuse needles.

Do not attempt to replace the cartridge in a pre-filled disposable pen.

Empty disposable pens must never be reused and must be properly discarded.

How long to use Toujeo Max SoloStar

Continue using Toujeo for as long as your doctor recommends.

Make sure you keep enough Toujeo Max SoloStar to last over weekends and holidays.

If you take too much (overdose) - Hypoglycaemia, a "Hypo"

If you accidentally use too much Toujeo Max SoloStar your blood sugar level may become too low (hypoglycaemia).

Immediately telephone your doctor or the Poisons Information Centre (13 11 26 in Australia; 0800 POISON or 0800 764 766 in New Zealand) if you think that you or

anyone else may have used too much Toujeo Max SoloStar.

Do this even if there are no signs of discomfort or poisoning.

The risk of hypoglycaemia is increased if you:

- accidentally use too much Toujeo Max SoloStar
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypoglycaemia can come on suddenly. They may include:

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

Always carry some sugary food or drink with you.

If you experience any of these symptoms of hypoglycaemia, you need to raise your blood sugar urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of a sugar-containing soft drink (not a diet soft drink)
- 2-3 concentrated glucose tablets

Follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk, when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood sugar level.

If not treated quickly, the initial symptoms of hypoglycaemia may progress to loss of co-ordination,

slurred speech, confusion, loss of consciousness and seizures.

If severe hypoglycaemia is not treated, it can cause brain damage and death.

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

It is important that they recognise the signs and symptoms of a "hypo".

Make sure they know to turn you on your side and get medical help immediately if you lose consciousness.

Make sure they know not to give you anything to eat or drink if you are unconscious.

This is because you could choke.

Provide them with the telephone number for your doctor, the Poisons Information Centre (13 11 26 in Australia; 0800 POISON or 0800 764 766 in New Zealand) and Emergency Services.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, have some sugary food or drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes educator, or the closest hospital.

If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you keep having "hypos" or if you have ever become unconscious after using Toujeo.

Your dose of Toujeo or other medicines may need to be changed.

If you miss a dose - Hyperglycaemia

If you forget to take your insulin dose, test your blood sugar level as soon as possible.

Toujeo Max SoloStar is a long-acting insulin and should be taken regularly at the same time each day. If you miss taking your dose at the regular scheduled time, your blood sugar levels may become high (hyperglycaemia).

However, taking a dose of Toujeo Max SoloStar at another time may increase your risk of having a hypo. You should therefore plan in advance with your doctor or healthcare professional so that you know what to do in case you miss a dose.

If you have missed a dose and are not sure what you should do, contact your doctor or healthcare professional for specific advice.

Do NOT use a double dose of your insulin.

If you double a dose, this may cause low blood sugar levels.

The risk of hyperglycaemia is increased if you:

- miss doses of Toujeo Max SoloStar or other insulin, or use less Toujeo Max SoloStar than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed
- take certain other medications

High blood sugar levels over a period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is very high or you experience any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual

- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and, in extreme cases, death if untreated.

Discuss any worries you may have about this with your doctor, pharmacist or diabetes educator.

While you are using Toujeo Max SoloStar

Things you must do

Measure your blood sugar level regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

It is important to keep using Toujeo Max SoloStar even if you feel well.

Toujeo Max SoloStar helps to control your condition, but does not cure it.

Tell your doctor if you often have hypoglycaemia or if you have ever become unconscious after using Toujeo Max SoloStar.

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

Always carry some sugary food or drink with you.

If you experience any of the symptoms of hypoglycaemia, immediately eat some sugary food or have a drink, e.g. jelly beans, sugar, honey, sugar-containing soft drink, glucose tablets. Diet and low calories

soft drinks do NOT contain sugar and are unsuitable to take for hypoglycaemia.

Make sure that you tell every doctor, dentist, pharmacist or other healthcare professional who is treating you that you have diabetes and are using Toujeo Max SoloStar.

Tell your doctor, pharmacist or diabetes educator if you are travelling.

Ask your doctor for a letter explaining why you are taking injecting pens and needles with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject Toujeo Max SoloStar and eat your meals at different times because of time differences in and between countries.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, e.g. sugar sachets or jelly beans
- carry emergency food rations in case of a delay, e.g. dried fruit, biscuits or muesli bars
- keep Toujeo Max SoloStar readily available; take enough Toujeo Max SoloStar for your expected needs whilst travelling - you may not be able to get Toujeo in the country you are visiting

Your doctor, pharmacist or diabetes educator can provide you with some helpful information. You may need to talk to them about

- Availability of your insulin in the country you are visiting
- Correct storage of your insulin while you are travelling
- Timing of meals and insulin administration while travelling
- The possible effects of changing to different time zones

- Possible new health risks in the countries to be visited
- What you should do in emergency situations when you feel unwell or become ill.

Tell your doctor if you are having trouble or difficulty with your eyesight.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Things you must not do

Do not stop using Toujeo Max SoloStar unless your doctor tells you to.

Do not skip meals while using Toujeo Max SoloStar.

Do not use Toujeo Max SoloStar if you think it has been frozen or exposed to excessive heat (temperatures above 30°C).

Do not give Toujeo Max SoloStar to anyone else, even if they have the same condition as you.

Do NOT use a syringe to withdraw from the cartridge of the pre-filled pen into the syringe.

Do NOT re-use needles

Things to be careful of

Be careful driving or operating machinery until you know how Toujeo Max SoloStar affects you. Be careful not to let your blood sugar levels fall too low.

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia.

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an

insulin plan for those times when you are sick.

If you become sick with a cold or flu, it is very important to continue using Toujeo Max SoloStar, even if you feel unable to eat your normal meal. If you have trouble eating solid foods, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for Toujeo Max SoloStar. Exercise may also speed up the effect of a dose of Toujeo Max SoloStar, especially if the exercise involves the area of the injection site (e.g. the thighs should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Side effects

Tell your doctor, pharmacist or diabetes educator as soon as possible if you do not feel well while you are using Toujeo Max SoloStar.

Toujeo Max SoloStar helps most people with diabetes, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, pharmacist or diabetes educator to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (hypoglycaemia - a "hypo").

Tell your doctor if you notice any of the following and they worry you:

- hypoglycaemia (mild to moderate)
- redness, swelling or itching at the injection site; usually these symptoms disappear within a few weeks during continued use
- a depression or thickening of the skin around the injection site (lipodystrophy); this can often occur if you inject too often at the same injection site

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

– **More severe symptoms of hypoglycaemia, including:**

- disorientation
- seizures, fits or convulsions
- loss of consciousness

– **Signs of a serious allergic reaction, including:**

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating

The above list includes some very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Toujeo Max SoloStar

Storage

All medicines should be kept where children cannot reach them.

Before use, keep unopened Toujeo Max SoloStar pre-filled pens in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

Before first use, store the pre-filled pen at room temperature for 1 to 2 hours. Once in use, the pre-filled pen should not be put in the refrigerator and it should be kept below 30°C. Do not leave it near heat or in direct light. Keep the pen cap to protect from light.

Discard the pre-filled pen within 42 days of first use. Pre-filled pens that are first carried as a spare for a while must also be discarded 42 days after being removed from the refrigerator.

Disposal

Dispose of your insulin syringes, needles and disposable injection devices safely into a sharp container.

If your doctor tells you to stop using Toujeo Max SoloStar or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Toujeo Max SoloStar is a pre-filled disposable pen containing a 3 mL cartridge.

Ingredients

Active Ingredient:

- insulin glargine (300 units/mL)

Inactive Ingredients:

- meta-cresol (preservative)
- glycerol
- zinc chloride
- hydrochloric acid
- sodium hydroxide
- water for injections

Supplier

Toujeo Max SoloStar is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a
Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644
Freecall: 0800 283 684

Email:
medinfo.australia@sanofi.com

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Further information

You can get more information about diabetes and insulin from:

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

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