

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PART III: PATIENT MEDICATION INFORMATION

TOUJEO® (Too-Jay-o) DoubleSTAR®

Insulin glargine (rDNA origin)

300 units/mL solution for subcutaneous injection in a prefilled pen (DoubleSTAR)

Read this carefully before you start taking TOUJEO 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 TOUJEO.

Serious Warnings and Precautions

- Hypoglycemia is the most common adverse effect of insulin, including TOUJEO.
- Glucose monitoring is recommended for all patients with diabetes.
- Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma, or death.
- Any change of insulin should be made cautiously and only under medical supervision.
- TOUJEO is not intended for intravenous or intramuscular administration.
- **TOUJEO must not be mixed with any other insulin or diluted with any other solution because it might not work as intended.**
- This insulin product should not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the vial or cartridge.
- Medication errors have been reported in which other insulins, particularly short-acting insulins, have been accidentally administered instead of insulin glargine. Insulin label must always be checked before each injection to avoid medication errors between insulin glargine and other insulins. Do not re-use needles and never use a syringe to remove TOUJEO from the DoubleSTAR prefilled pen as regular insulin syringes are not graduated for TOUJEO.

What is TOUJEO used for?

- TOUJEO is a long-acting man-made insulin used to control high blood sugar in patients 6 years of age and older with diabetes mellitus.
- TOUJEO contains 3 times as much insulin in 1 mL as standard insulin (100 U/mL).
- TOUJEO is not for use to treat diabetic ketoacidosis.

How does TOUJEO work?

Diabetes is a disease in which the body does not produce or not enough insulin to control the level of blood glucose. TOUJEO is a long-acting human insulin analogue which lowers your blood glucose level.

What are the ingredients in TOUJEO?

Medicinal ingredients: The active ingredient in TOUJEO is insulin glargine (rDNA origin).

Non-medicinal ingredients are: glycerol 85%, m-cresol, water, zinc chloride, hydrochloric acid and sodium hydroxide for pH adjustment.

TOUJEO comes in the following dosage form:

TOUJEO is a solution for injection (300 U/mL) and is available in the following package size:

- TOUJEO SoloSTAR: 1.5 mL prefilled disposable pen, package of 3 or 5.
- TOUJEO DoubleSTAR: 3 mL prefilled disposable pen, package of 2 or 3.

Do not use TOUJEO:

- If you are allergic to this drug or to any ingredient in the formulation or component of the container;
- If you have diabetes ketoacidosis;
- If you are having an episode of low blood sugar (hypoglycemia);
- For intravenous or intramuscular injections.

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

- Have renal or hepatic impairment;
- Have any endocrine disease such as: acromegaly (too much growth hormone), Cushing's syndrome (too much of the adrenal hormones or long-time use of cortisone-type drugs), hyperthyroidism (hyperfunction of the thyroid gland), pheochromocytoma (tumor of the adrenal gland);
- Have any psychiatric disease;
- Have any blood vessels disease, such as narrowing of the heart blood vessels (coronary arteries) or of the blood vessels supplying the brain;
- Have an eye disease called proliferative retinopathy;
- Are currently consuming alcohol;
- Are currently taking any medicine, including other types of insulins;
- Take other medicines, especially ones called TZDs (thiazolidinediones);
- Have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with TOUJEO;
- Are planning to have a baby, are pregnant or are nursing a baby. It is not known if TOUJEO may harm your unborn or breastfeeding baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Before you start using TOUJEO, talk to your healthcare provider about low blood sugar and how to manage it.

Other warnings you should know about:

TOUJEO (300 U/mL) and LANTUS (100 U/mL) contain the same active ingredient. Although TOUJEO contains the same active substance as insulin glargine 100 U/mL (LANTUS), these drugs are not interchangeable. The switch from one insulin therapy to another requires medical prescription, medical supervision and blood glucose monitoring. Please, consult your doctor for further information.

Concomitant oral antidiabetic treatment may need to be adjusted.

High blood sugar (hyperglycemia) or Low blood sugar (hypoglycemia) with Changes in Insulin Regimen.**Never Share a TOUJEO DoubleSTAR pen Between Patients.**

Low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include: dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change, hunger.

Severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction: a rash over your whole body, trouble breathing, a fast heartbeat, or sweating.

Edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Heart failure. Taking certain diabetes pills called TZDs (thiazolidinediones) with TOUJEO may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with TOUJEO. Your healthcare provider should monitor you closely while you are taking TZDs with TOUJEO. Tell your healthcare provider if you have any new or worse symptoms of heart failure including: shortness of breath, swelling of your ankles or feet, sudden weight gain. Treatment with TZDs and TOUJEO may need to be changed or stopped by your healthcare provider if you have new or worse heart failure.

The combination of Insulin, including TOUJEO, with a TZD is not indicated for the treatment of Type 2 Diabetes Mellitus.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are using potassium lowering drugs or losing potassium through other means (e.g. diarrhea). Symptoms of hypokalemia may include: Fatigue, muscle weakness or spasms, constipation, tingling or numbness, feeling of skipped heart beats or palpitations.

If you have diabetic retinopathy (condition affecting the retina of the eye) and you have a marked change in blood glucose levels, the retinopathy may temporarily get worse. Ask your doctor about this.

Accidental mix-ups between insulin glargine and other insulins, particularly short-acting insulins, have been reported. To avoid medication errors between insulin glargine and other insulins, check your insulin labels before every injection.

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 TOUJEO:

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 (hypoglycemia) if you take:

- any other medicine to treat diabetes;
- medicines used to treat high blood pressure and/or heart problems, such as: angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blocking (ARB) agents, disopyramide;
- sulfonamide antibiotics;
- fibrates (medicines used for lowering high levels of blood fats);
- monoamine oxidase inhibitors (MAOIs) (medicines used to treat depression);
- medicines used to relieve pain and lower fever, such as pentoxifylline, propoxyphene and salicylates (such as acetylsalicylic acid);
- somatostatin analogs, such as octreotide.

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

- medicines used to treat mental health problems, such as: olanzapine, clozapine;
- hormones, such as: estrogens and/or progesterone (alone or as contraceptive pills), somatotropin, thyroid hormones, glucagon;
- corticosteroids, such as cortisone;
- danazol (a medicine used to treat endometriosis);
- protease inhibitors (used to treat HIV infection);
- diuretics (also called water pills), used to treat high blood pressure or fluid retention;
- isoniazid (used to treat tuberculosis);
- some medicines used to treat asthma, such as albuterol, epinephrine, terbutaline.

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

- high blood pressure medicines, such as: beta-blockers or clonidine;
- some medicines used to treat mental health problems, such as: lithium salts;
- alcohol;
- a medicine used to treat some parasitic infections, called pentamidine. This may cause too low blood sugar which is sometimes followed by too high blood sugar.

Some medicines may make harder to recognize the warning signs of your blood sugar being too low (hypoglycemia). Such medicines include: beta-blockers medicines, clonidine, guanethidine, or reserpine.

Do not use insulin together with medicines used to treat type 2 diabetes belonging to a class called Thiazolidinediones (TZDs). The use of these medicines together may increase your risk of developing heart failure.

How to take TOUJEO:

Read the detailed “Instructions for Use” that come with your TOUJEO DoubleSTAR disposable prefilled pen. Use TOUJEO exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much TOUJEO 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;
- TOUJEO comes in a DoubleSTAR disposable prefilled pen that you must use to give your TOUJEO. The dose counter on your pen shows your dose of TOUJEO. **Do not** make any dose changes unless your healthcare provider tells you to;
- TOUJEO is injected under your skin (subcutaneously);
- Change (rotate) your injection sites within the area you chose with each dose;
- **Do not** use the exact spot for each injection;
- **Do not** use TOUJEO in an insulin pump or inject TOUJEO into your vein (intravenously);
- **Do not** mix TOUJEO with any other type of insulin or liquid medicine;
- **Keep TOUJEO and all medicines out of the reach of children.**

TOUJEO is a clear solution and looks like some short-acting insulins. Always check for the name of the insulin on your carton and your TOUJEO DoubleSTAR 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 TOUJEO DoubleSTAR 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 TOUJEO to be injected. **No dose re-calculation is required.**

The TOUJEO DoubleSTAR pen delivers doses of 2–160 units per injection, in steps of 2 units.

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.

Never use a syringe to remove TOUJEO from the pen as regular insulin syringes are not graduated for TOUJEO.

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 TOUJEO DoubleSTAR prefilled 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.

Preparing the Dose

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 TOUJEO and other insulins, check the label on your TOUJEO DoubleSTAR 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.** TOUJEO 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 TOUJEO DoubleSTAR pen before use.**
6. **Always attach a new needle.** Follow the TOUJEO DoubleSTAR “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 TOUJEO DoubleSTAR “Instructions for Use” to ensure the correct dose of TOUJEO 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 TOUJEO 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 5.** 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 TOUJEO DoubleSTAR “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:

Dosage

- The dosage of TOUJEO should be individualized and determined based on your health professional’s advice in accordance with your needs. Your healthcare provider should tell you how much TOUJEO to use and when to use it.
- Use TOUJEO exactly as your healthcare provider tells you to.
- TOUJEO should be used 1 time each day and at the same time each day.
- **Do not** change the amount of TOUJEO you use unless your healthcare provider tells you to.
- **Your dose of TOUJEO may need to change because of** a change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

Overdose:

If you **have injected too much TOUJEO**, your blood sugar level may become too low (hypoglycemia). Check your blood sugar frequently. **If your blood sugar gets too low, take action to increase your blood sugar level straight away. See advice “What to do if you experience hypoglycemia?” below.**

If you think you have taken too much TOUJEO, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you **have missed a dose of TOUJEO** or if you **have not injected enough insulin**, your blood sugar level may become too high (hyperglycemia). Check your blood sugar frequently. For information on the treatment of hyperglycemia, see “What to do if you experience hyperglycemia” below.

Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using TOUJEO?

These are not all the possible side effects you may feel when taking TOUJEO. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

The following side effects may be observed while taking TOUJEO:

- Common (may affect up to 1 in 10 people)
 - hypoglycemia (see also Hypoglycemia section below);
- Rare (may affect up to 1 in 1,000 people)
 - hyperglycemia (see also Hyperglycemia section below);
 - skin changes and reactions at the injection site (see also Injection site reactions section below);
 - allergic reactions (see also Allergic reactions section below);
 - swelling in the calves and ankles (due to built-up of water in the body);
 - vision changes.

Weight gain has occurred with some insulin therapies including TOUJEO.

Hypoglycemia (low blood sugar level)

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

- intercurrent conditions (illness, stress, or emotional disturbances);
- accidental injection of an increased insulin dose;
- malfunction and/or misuse of medical devices;
- too-low food intake, or skipped meals;
- an increase in exercise;
- a new insulin type or schedule;
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs.

Symptoms of mild to moderate hypoglycemia may occur suddenly and can include:

- abnormal behavior (anxiety, irritability, restlessness, trouble concentrating, personality changes, mood changes, confusion or nervousness);
- fatigue;
- tingling in your hands, feet, lips, or tongue;

- tremor (shaking);
- unsteady gait (walking);
- dizziness, light-headedness, or drowsiness;
- headache;
- blurred vision;
- slurred speech;
- palpitations (rapid heartbeat);
- cold sweat;
- pale skin;
- nightmares or trouble sleeping;
- nausea;
- hunger.

Mild to moderate hypoglycemia may be treated by consuming foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy, juice or glucose tablets, prominently labelled for rescuers. Contact your health-professional about appropriate proportions of carbohydrates.

Signs of severe hypoglycemia can include:

- disorientation;
- convulsions;
- loss of consciousness, coma;
- seizures.

Severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious may require an injection of glucagon or should be treated with intravenous administration of glucose by medical personnel. Without immediate medical help, serious reactions, even death, may occur.

The early warning symptoms of hypoglycemia may be changed, less pronounced, or even absent, for example, in patients whose sugar levels are markedly improved, elderly patients, patients with diabetic nerve disease, patients with a long history of diabetes or patients receiving treatment with certain other drugs. Such situations may result in severe hypoglycemia (and possibly loss of consciousness) before a patient exhibits any symptoms.

Some people may not recognize when their blood sugar drops too low. Often the first sign of this is confusion or loss of consciousness. Educational and behavioural programs, including blood glucose awareness training, may help improve your ability to detect hypoglycemia and reduce the frequency of severe hypoglycemia.

Without recognition of early warning symptoms, you may not be able to take steps to avoid more serious hypoglycemia. Be alert for all of the various types of symptoms that may indicate hypoglycemia. Patients who experience hypoglycemia without early warning symptoms should monitor their blood glucose frequently, especially prior to activities such as driving a car or use mechanical equipment. If the blood glucose is below your normal fasting glucose, you should consider eating or drinking sugar-containing foods to treat your hypoglycemia.

Other people may develop hypoglycemia during the night – this is called nocturnal hypoglycemia. It is fairly common and lasts over 4 hours. Because the person is usually asleep when it occurs, nocturnal hypoglycemia can go undetected, resulting in an increased risk of severe hypoglycemia compared to the daytime. To help reduce your risk of asymptomatic nocturnal hypoglycemia, your doctor may ask you to periodically monitor your overnight blood glucose levels.

If you have frequent episodes of hypoglycemia, experience difficulty in recognizing the symptoms, or if your diabetes is getting worse, you should consult your health professional to discuss possible changes in therapy, meal plans, and/or exercise programs to help you avoid hypoglycemia.

What to do if you experience hypoglycemia?

- Do not inject insulin. Take about 10 to 20 grams sugar straight away - such as glucose, sugar cubes or a sugary-drink. Do not drink or eat foods that contain artificial sweeteners (such as diet drinks). They do not help treat low blood sugar.
- Eat something (such as bread or pasta) that will raise your blood sugar over a longer time. Ask your doctor or nurse if you are not sure which foods you should eat. With TOUJEO, it may take longer to recover from low blood sugar because it is long-acting.
- Speak to a doctor straight away if you are not able to control the hypoglycemia, or it comes back again.

Get emergency medical help if you have: trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

What other people should do if you have hypoglycemia

Tell your relatives, friends and close colleagues to get medical help straight away if you are not able to swallow or if you pass out (become unconscious).

You should test your blood sugar straight away after taking glucose to check that you really have hypoglycemia.

Hyperglycemia

Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin.

Hyperglycemia can be brought about by:

- intercurrent conditions (illness, stress, or emotional disturbances);
- not taking your insulin or taking less than recommended by your health professional;
- malfunction and/or misuse of medical devices;
- eating significantly more than your meal plan suggests;
- a new insulin type or schedule;
- some new medications, including prescriptions, over-the counter medication, herbs, vitamins and street drugs.

Symptoms of hyperglycemia include:

- confusion or drowsiness;
- increased thirst;
- decreased appetite, nausea, or vomiting;
- rapid heart rate;
- increased urination and dehydration (too little fluid in your body);
- blurred vision;
- flushed dry skin;
- acetone odour of breath.

Hyperglycemia can be mild or severe. It can **progress to high glucose levels, diabetic ketoacidosis (DKA), and result in unconsciousness and death.**

What to do if you experience hyperglycemia

- Test your blood sugar level and your urine for ketones as soon as you notice any of the above signs;
- Contact your doctor straight away if you have severe hyperglycemia or ketoacidosis.

Diabetic ketoacidosis (DKA)

The first symptoms of diabetic ketoacidosis usually come on over a period of hours or days. With ketoacidosis, urine tests show large amounts of glucose and acetone.

Symptoms of diabetic ketoacidosis include:

First symptoms:

- drowsiness;
- flushed face;
- thirst;
- loss of appetite;
- fruity smelling breath;
- rapid, deep breathing;
- abdominal (stomach area) pain.

Severe symptoms:

- heavy breathing;
- rapid pulse.

Prolonged hyperglycemia or diabetic ketoacidosis can lead to:

- nausea;
- vomiting;
- dehydration;
- loss of consciousness;
- death.

Severe or continuing hyperglycemia or DKA requires prompt evaluation and treatment by your health professional. TOUJEO should not be used to treat DKA, and the persons treating you should be advised you are taking a long-acting insulin and about your regimen.

Allergic reactions

A patient may be allergic to an insulin product **including TOUJEO**. Severe insulin allergies may be life-threatening. If you **have any signs or symptoms of severe allergic reactions**, seek medical help immediately.

Signs of **severe** allergy include:

- a rash all over your body;
- shortness of breath;
- wheezing (trouble breathing);
- a fast pulse;
- sweating;
- low blood pressure.

Injection site reactions

Injecting insulin **including TOUJEO** can cause the following reactions on the skin at the injection site:

- a little depression in the skin (lipoatrophy);
- skin thickening (lipohypertrophy);
- redness, pain, swelling, itching, hives, or inflammation at injection site.

You can reduce the chance of getting an injection site reaction if you change the injection site each time. If you have local injection site reactions, contact your health-professional.

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.

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON (may affect up to 1 in 10 people)			
Severe hypoglycemia			✓
RARE (may affect up to 1 in 1,000 people)			
Allergic reactions			✓
Hyperglycemia		✓	
Vision changes		✓	

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/adverse-reaction-reporting.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:

Before first use

- Keep new TOUJEO DoubleSTAR pens in a fridge, between 2°C to 8°C;
- Do not freeze. If TOUJEO DoubleSTAR freezes or overheats, discard it immediately.

After first use

- Keep your opened TOUJEO DoubleSTAR pen at room temperature (15 - 30°C), below 30°C;
- Never put your pen back in the fridge;
- Never store your pen with the needle attached;
- Store your pen with the cap on;
- Your pen can be stored for up to 42 days (6 weeks) away from direct heat and light, as long as the temperature is not greater than 30°C. If the TOUJEO DoubleSTAR pen overheats or if there is any remaining insulin after 42 days, discard it.

Opened TOUJEO DoubleSTAR should not be stored in the freezer and should not be allowed to freeze. If TOUJEO DoubleSTAR freezes, discard it.

Do not use a TOUJEO DoubleSTAR after the expiration date stamped on the label or if it is cloudy or if you see particles.

As with all medications and devices, keep out of reach and sight of children.

If you want more information about TOUJEO:

- 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.html>); sanofi-aventis Canada Inc.'s website (www.sanofi.ca), or by calling 1-888-852-6887.

This document is available in large print format by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-888-852-6887.

The size of the large print can be further enlarged if needed.

sanofi-aventis Canada Inc.
Toronto, Ontario
M2R 3T4

This leaflet was prepared by sanofi-aventis Canada Inc.

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INSTRUCTIONS FOR USE: TOUJEO® DOUBLESTAR®

This pen is recommended for patients requiring at least 20 units per day.

Read this first

Do not share your TOUJEO DoubleSTAR pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

TOUJEO contains 300 Units/mL insulin glargine.

- **Do not re-use needles.** If you do you might not get your dose (underdosing) or get too much (overdosing) as the needle could block.
- **Do not use a syringe to remove insulin from your pen.** If you do you will get too much insulin. The scale on most syringes is made for non-concentrated insulin only.
- The dose selector of your TOUJEO DoubleSTAR pen dials by **2 units**.

People who are blind or have vision problems should not use the TOUJEO DoubleSTAR pen without help from a person trained to use the TOUJEO DoubleSTAR pen.

Important information

Do not use your pen if it is damaged or if you are not sure that it is working properly.

- Always perform a safety test (see **Step 3**).
- Always carry a spare pen and spare needles in case they are lost or stop working

Learn to inject

Talk with your healthcare provider about how to inject, before using your pen.

- 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?

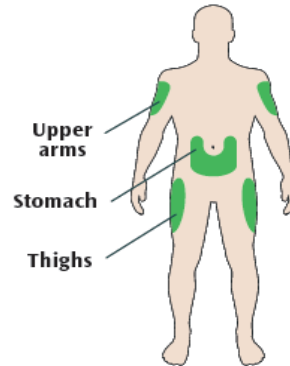
If you have any questions about your pen or about diabetes, ask your healthcare provider, or call sanofi-aventis Canada Inc at 1-888-852-6887.

Extra items you will need:

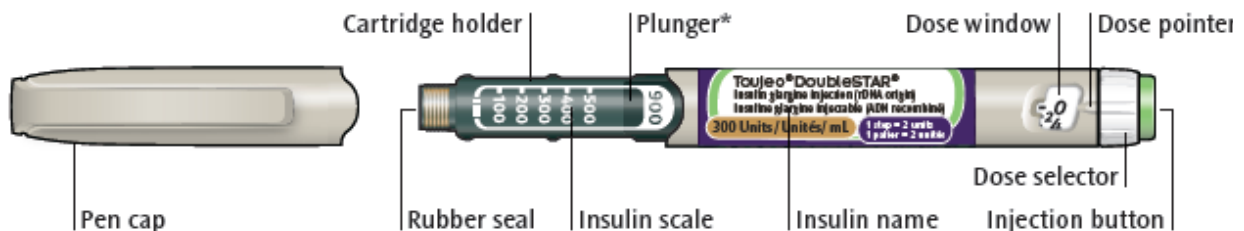
- a new sterile needle (not included with the pen) (see **Step 2**).
- an alcohol swab.
- a puncture-resistant container for used needles and pens (see **Throwing your pen away**).

Places to inject

- Inject your insulin exactly as your healthcare provider has shown you.
- Inject your insulin under the skin (subcutaneously) of your upper legs (thighs), upper arms, or stomach area (abdomen).
- Change (rotate) your injection sites within the area you choose for each dose.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.



Get to know your pen



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

Step 1: Check your pen

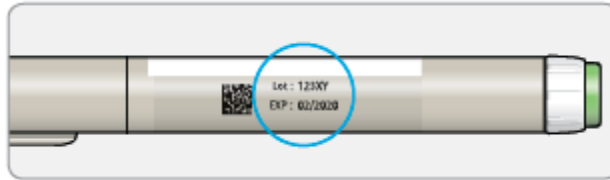
Take a new pen out of the refrigerator at least **1** hour before you inject. Cold insulin is more painful to inject.

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

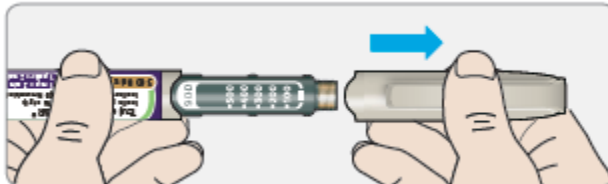
- **Make sure you have the correct insulin.**



- **Do not** use your pen after the expiration date printed on the label.



1.B Pull off the pen cap.



1.C Check that the insulin is clear.

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



1.D Wipe the rubber seal with an alcohol swab.



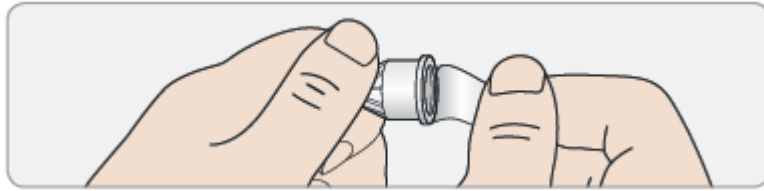
If you have other injector pens

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

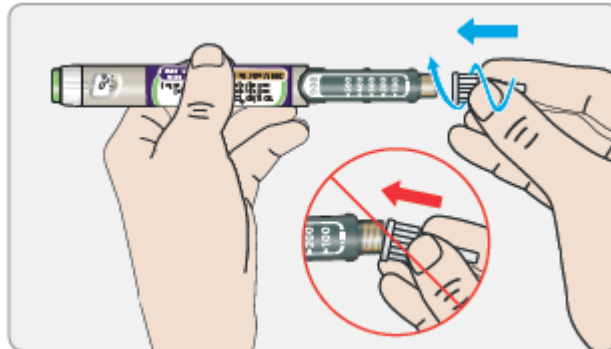
Step 2: Attach a new needle

- **Do not** re-use needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
- Always use needles* from BD (such as BD Ultra-Fine[®]), Ypsomed (such as Clickfine[®]), or Owen Mumford (such as Unifine[®] Pentips[®]) that are 8 mm long or shorter.

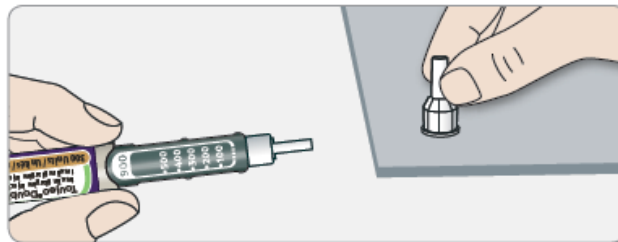
2.A Take a new needle and peel off the protective seal.



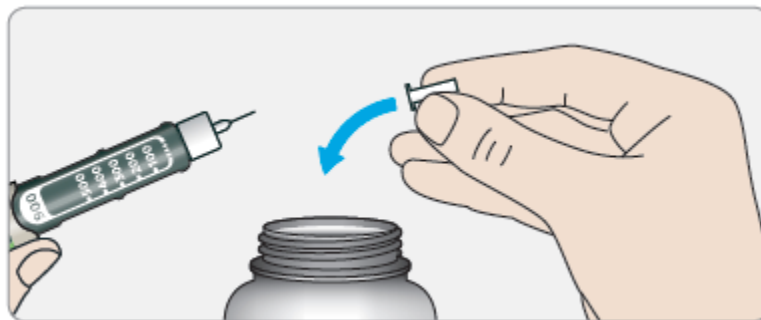
2.B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



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



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



Handling needles

- Be careful when you are handling needles to help prevent accidental needle-stick injury. You may give other people a serious infection, or get a serious infection from them.

Step 3: Do a safety test

Always do a safety test before each injection to:

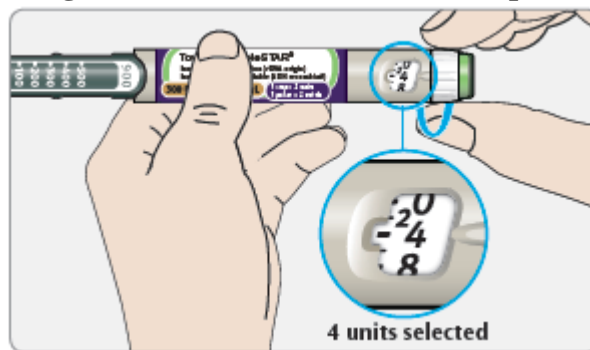
- check your pen and the needle to make sure they are working properly.
- make sure that you get the correct insulin dose.

If the pen is new, you must perform safety tests before you use the pen for the first time 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.

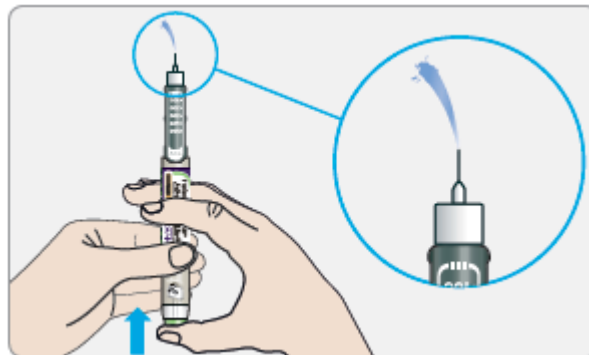
If you do not see insulin coming out before taking your dose, you could get an underdose or no insulin at all. This could cause high blood sugar.

3.A Select 4 units by turning the dose selector until the dose pointer is at the 4 mark.



3.B Press the injection button all the way in.

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



If no insulin appears:

- You may need to repeat this step up to **6** times before seeing insulin.
- If no insulin comes out after the sixth 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.
- **Do not** use a syringe to remove insulin from your pen.

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

- **Do not** select a dose or press the injection button without a needle attached. This may damage your pen.
- TOUJEO DoubleSTAR is made to deliver the number of insulin units that your healthcare provider prescribed. You **do not need to do any dose calculations**.
- The dose selector of your TOUJEO DoubleSTAR pen dials by 2 units and can only dial even doses of insulin. This pen is recommended for patients requiring at least 20 units per day.

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



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

- Set the dose by turning the dose selector to a line in the dose window. Each line equals 2 units.
- The dose selector clicks as you turn it.
- Always check the number in the dose window to make sure you dialed the correct dose.
- **Do not** dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.
- 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, split the dose into **2** injections or use a new pen. If you use a new pen, perform a safety test (see **Step 3**).



How to read the dose window

The dose selector dials by 2 units.

Each line in the dose window is an even number.



60 units selected



58 units selected

Units of insulin in your pen

- Your pen contains a total of **900** units of insulin. You can select doses from **2** to **160** units. The dose is adjusted by 2 units at a time. Each pen contains more than 1 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

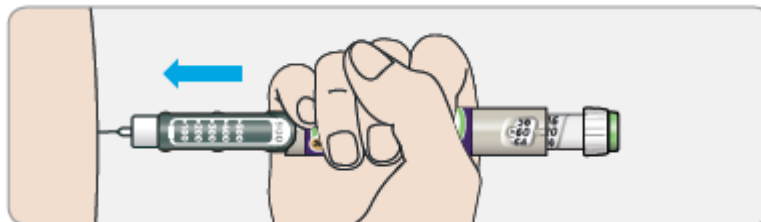
If you find it hard to press the injection button in, **do not** force it as this may break your pen. See the section below for help.

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

- The site you choose for the injection should be clean and dry.
- If your skin is dirty, clean it as instructed by your healthcare provider.

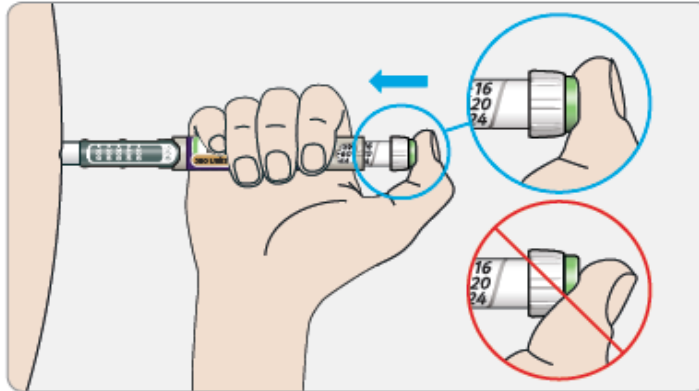
5.B Push the needle into your skin as shown by your healthcare provider.

- **Do not** touch the injection button yet.



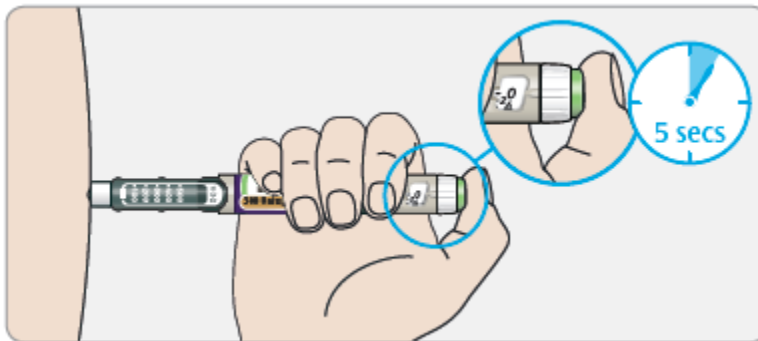
5.C Place your thumb on the injection button. Then press all the way in and hold.

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



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

- This will make sure you get your full dose.



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

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

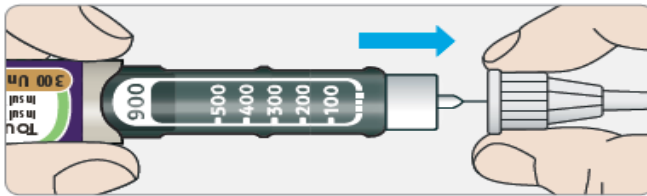
- Change the needle (see **Step 6** and **Step 2**) then do a safety test (see **Step 3**).
- If you still find it hard to press in, get a new pen.
- **Do not** use a syringe to remove insulin from your pen.

Step 6: Remove the needle

- Take care when handling needles to prevent needle injury and cross-infection.
- **Do not** put the inner needle cap back on.

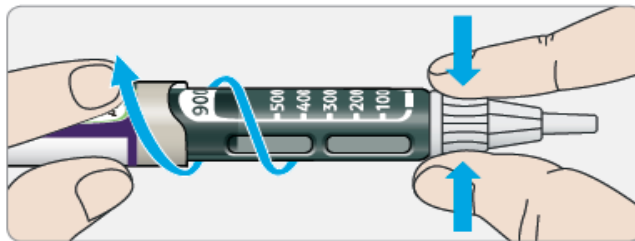
6.A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap. Then push firmly on.

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

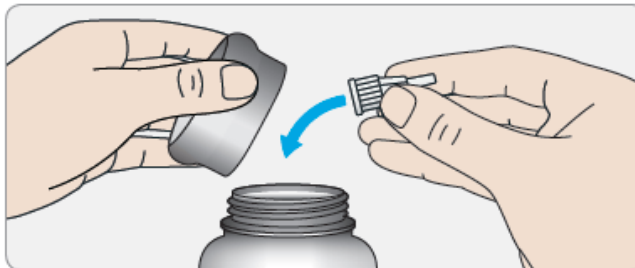


6.B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.

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

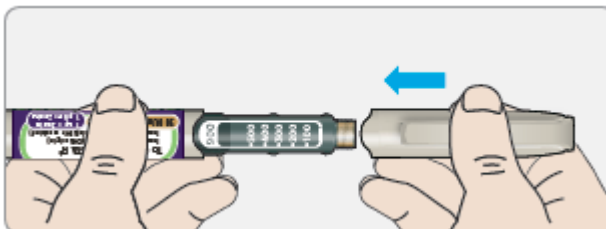


6.C Throw away the used needle in a puncture-resistant container (see “Throwing your pen away” at the end of this Instructions for Use).



6.D Put the pen cap back on.

- **Do not** put the pen back in the refrigerator.



Use by

- Only use your pen for up to **42 days** after its first use.

How to store your pen

Before first use

- Keep new pens in the refrigerator between **2°C and 8°C**.
- **Do not** freeze.

After first use

- Keep your pen at room temperature (15- 30°C), below 30°C.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached.
- Store your pen with the pen cap on.
- Keep TOUJEO DoubleSTAR pens and needles out of the 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 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 the pen in a puncture-resistant container.
- Dispose of used container according to your local regulations.

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