

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Toujeo Solution for subcutaneous injection in DoubleStar pen

Active ingredient: Each pre-filled DoubleStar pen contains 300 units/ml of insulin glargine.

Each DoubleStar pen supplies 2-160 units, in 2-unit intervals. Inactive ingredients: see section 6.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor, pharmacist or nurse.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Toujeo is a solution for injection that contains insulin glargine. Insulin glargine is a modified insulin and is very similar to human insulin.

Toujeo 300 units/ml contains 3 times more insulin per ml than standard insulin (100 units/ml).

Toujeo is used for treatment of diabetes in adults. Diabetes is a disease in which the body does not produce enough insulin to control blood sugar.

Toujeo lowers your blood sugar steadily over a long period of time. It is used for once-daily dosing. If necessary, you can change your injection time. This is because this medicine lowers your blood sugar over time (see section 3).

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to insulin glargine or to any of the other ingredients of this medicine (see section 6).

Special warnings regarding use of the medicine

Talk with the doctor, pharmacist or nurse before commencing use of Toujeo.

Strictly follow the instructions regarding dosage, monitoring (blood and urine tests), diet and physical activity (physical work or exercise), and injection technique that you received from the doctor.

Be especially aware of the following issues:

- Blood sugar levels that are too low (hypoglycemia). If your blood sugar level is too low, follow the instructions for hypoglycemia (see the explanation in the box at the end of this leaflet).
- If you switch from another type, brand or manufacturer of insulin, your insulin dosage may need to be changed.
- Pioglitazone. See "Use of pioglitazone together with insulin".
- Ensure that you are using 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 insulin preparations.
- Never use a syringe to remove Toujeo from your DoubleStar pen. This is to avoid dosage errors and possibility of overdose, which can lead to a low sugar level. See section 3.
- To avoid an insulin underdose, perform safety tests before the first use of a new pen and also before every use of the pen (see step 3 of instructions for use). See also section 3.
- If you are blind or have impaired eyesight, do not use the pen without help. This is because you will not be able to read the dose window on the pen. Get help from someone who has good eyesight and who has been trained to use 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 well if you inject into a lumpy area (see "How should you use the medicine"). If you are currently injecting into a lumpy area, contact your doctor 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 dosage or the dosage of your other antidiabetic medications.

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 (hyperglycemia).
- If you do not eat enough – your blood sugar level may be too low (hypoglycemia).

In most cases, you will need to see a doctor. Contact a doctor as soon as you feel ill or are injured.

If you have type 1 diabetes (insulin-dependent diabetes), and you are ill or are suffering from an injury:

- do not stop your insulin.
- continue to consume enough carbohydrates.

Always tell people who are caring for you or treating you that you have diabetes.

Treatment with insulin may cause the body to produce antibodies to insulin (substances that act against insulin); however, only in rare cases will a change in the insulin dosage be required.

Travel

Before traveling, talk with your doctor. You may need to talk about:

- the availability of your type of insulin in the country you are visiting,
- supply of insulin, needles and other items,
- correct storage of insulin while traveling,
- timing of meals and of insulin use,
- the possible effects of changing to different time zones,
- any health risks in the countries you will visit,
- what you should do in emergency situations, when you do not feel well or become ill.

Children and adolescents

This medicine is not intended for children and adolescents below 18 years of age.

Other medicines and Toujeo

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Some medicines can cause a change in your blood sugar level. It may be necessary to adjust your insulin dosage.

Before taking a medicine, ask the doctor if it can affect your blood sugar level and what action, if any, you need to take. You must also be careful when you stop taking another medicine.

In particular, inform the doctor or pharmacist if you are taking:

- **Your blood sugar level may fall (hypoglycemia) if you take:**
- any other medicine to treat diabetes.
- disopyramide (for certain heart diseases).
- fluoxetine (for depression).
- sulfonamide antibiotics.
- fibrates (to lower high blood lipid levels).
- monoamine oxidase (MAO) inhibitors (for depression).
- ACE inhibitors (for heart diseases or high blood pressure).
- medicines to relieve pain and lower fever, such as paracetamol, propoxyphene, salicylates (such as aspirin).
- pentamidine (for certain infections caused by parasites). This may cause too low a blood sugar level, which can sometimes be followed by too high a blood sugar level.

Your blood sugar level may rise (hyperglycemia) 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 level).
- isoniazid (for tuberculosis).
- somatropin (growth hormone).
- thyroid hormones (for thyroid gland disorders).
- estrogens and progestogens (present, for example, in birth control pills).
- olanzapine, clozapine and phenothiazine derivatives (for mental problems).
- sympathomimetic medicines (such as epinephrine [adrenaline], salbutamol, terbutaline, for asthma).

Blood sugar level may either rise or fall if you take:

- beta-blockers or clonidine (for high blood pressure).
- lithium salts (for mental problems).

Beta-blockers, like other sympatholytic medicines (such as clonidine, guanethidine, and reserpine – for high blood pressure), may make it more difficult to identify the warning signs of too low blood sugar level (hypoglycemia). They may even mask or suppress the first warning signs of too low a blood sugar level. **Use of pioglitazone together with insulin** – some patients with long-standing type 2 diabetes and heart disease or previous stroke, who were treated with pioglitazone and insulin, developed heart failure. If you experience signs of heart failure, such as unusual shortness of breath, rapid weight gain or localized swelling (edema), refer to the doctor as soon as possible. If you are not sure whether you are taking any of these medicines, ask your doctor or pharmacist.

Use of the medicine with alcohol

Your blood sugar level may rise or fall if you drink alcohol. Check your blood sugar level more often than usual.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before taking any medicine. Inform your doctor if you are pregnant, think you are pregnant, are planning to become pregnant or are breastfeeding. Your insulin dosage may have to be changed during pregnancy and after giving birth. Strict control of your diabetes and prevention of hypoglycemia are particularly important for your baby's health.

If you are breastfeeding, consult your doctor, as you may require a change in your insulin dosage and diet.

Driving and operating machinery

Sugar levels that are too low or too high or eyesight problems can affect your ability to drive or operate machinery.

Your ability to concentrate may be affected. This can be dangerous to you and to others.

Consult the doctor regarding driving if:

- your blood sugar level is often too low.
- you find it hard to recognize when your blood sugar is too low.

Important information regarding some of the ingredients of Toujeo

This medicine contains less than 1 mmol (23 mg) sodium ions per ml; this means it is essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine exactly according to the doctor's instructions. Check with the doctor, nurse or pharmacist if you are uncertain.

Although Toujeo contains the same active ingredient as insulin glargine 100 units/ml, do not switch between the medicines. Switching from one insulin treatment to another requires a medical prescription, medical supervision and monitoring of sugar levels. For further information, consult the doctor.

How much to use

The Toujeo DoubleStar pen can provide a dose of 2 to 160 units per injection, at intervals of 2 units. The pen is recommended for patients who need at least 20 units of insulin per day (see also section 2).

The dose window of the DoubleStar pen shows the number of Toujeo units to be injected. Do not recalculate the dose. Based on your lifestyle, results of your blood sugar tests and your previous insulin use, the 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 perform urine tests,
- when you may need to inject 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 used to treat high blood sugar levels.

If you use more than one insulin, always make sure that you are using the correct insulin by checking the label of the insulin 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 is highlighted in gold-honey color on the label of your Toujeo DoubleStar pre-filled pen.

Ask the doctor or pharmacist if you are uncertain.

Many factors may affect your blood sugar level. You should be familiar with these factors so that you can respond appropriately to changes in your blood sugar level and prevent it from getting too high or too low. For more information, see the explanation in the box at the end of this leaflet.

Flexibility in time of administration

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

Use in the elderly (65 years and over)

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

If you have kidney or liver problems

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

Before injecting

- Carefully read the instructions for use included in this leaflet.
- If you do not follow all of these instructions, you may receive too much or too little insulin.
- Perform a safety test as described in Step 3 of the Instructions for Use. If you do not do one, you will not receive your full dose. If this occurs, you should increase the frequency of checking your blood sugar level and might need to administer additional insulin. Also see section 2.

How to inject

- Toujeo is injected under the skin (subcutaneous - SC).
 - Inject Toujeo into the front of the thighs, upper arms or in the front of the waist (abdomen).
 - Change the place within the area you inject each day to lower the risk of shrinking or thickening of the skin (see section 4).
- To prevent possible transmission of diseases, do not use the same insulin pen for more than one patient, even if the needle is changed.

Always use a new sterile needle for each injection. Do not reuse needles. Reuse of needles increases the risk of their blockage and of you getting too much or too little insulin.

Do not use Toujeo

- in a vein. This will change its activity and may cause hypoglycemia.
- in an insulin pump.
- if there are particles in the insulin. The solution should be clear, colorless and with a water-like texture.

Never use a syringe to remove Toujeo from your DoubleStar pen, as it may cause a severe overdose. See section 2.

Do not use the DoubleStar pen if it is damaged, was not stored properly, does not work properly, or if you notice there is an unexpected worsening of control of your blood sugar levels.

- Discard it and use a new pen.
- If you think there is a problem with your pen, consult the doctor, pharmacist or nurse.

If you used more Toujeo than required

If you injected too much Toujeo, your blood sugar level may be too low (hypoglycemia). Check your blood sugar level and eat more food to prevent your blood sugar level from getting too low. See instructions for treating hypoglycemia at the end of the leaflet.

If you forgot to use Toujeo

When necessary, Toujeo can be injected up to 3 hours before or after the time you usually inject it throughout the day.

If you skipped a Toujeo dose, or if you did not inject enough insulin, your blood sugar level may be too high (hyperglycemia):

- Do not inject a double dose to compensate for a forgotten dose.
- Check your blood sugar level and then inject the next planned dose at the regular time.
- See instructions for treating hyperglycemia in the box at the end of the leaflet.

If you stopped using Toujeo

Do not stop using Toujeo without consulting the doctor.

Discontinuation of use may lead to a very high blood sugar level and ketoacidosis (build-up of acid in the blood).

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Toujeo may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

If you notice signs indicating that your blood sugar level is too low (hypoglycemia), take action to increase your blood sugar level straight away (see the box at the end of the leaflet). Hypoglycemia 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 level falls too much, you may become unconscious.
- Very low sugar level may cause brain damage and may be life-threatening.
- For further information, see the box at the end of the leaflet.

Severe allergic reactions (rare, may affect up to 1 in 1000 people). Symptoms can include rash and itching all over the body, swelling of the skin or mouth, shortness of breath, feeling faint (a sharp drop in blood pressure) with fast heartbeats and sweating. Severe allergic reactions may be life-threatening. Refer to the doctor immediately if you experience signs of a severe allergic reaction.

Other side effects

Refer to the doctor, pharmacist or nurse if you experience any of the following side effects:

• Skin changes at the injection site:

If you inject insulin too often in the same place, the skin may either shrink (lipoatrophy) (*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 form from build-up of a protein called amyloid (cutaneous amyloidosis; unknown frequency). The insulin that you inject may not work well if injected into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Common side effects (may affect up to 1 in 10 people):

- Skin and allergic reactions at the injection site: The signs can include redness, unusually intense pain when injecting, itching, rash, swelling or inflammation. The reactions may also spread around the injection site. Most minor reactions to insulins usually disappear within a few days to a few weeks.

Rare side effects (may affect up to 1 in 1000 people):

- Eye reactions: A marked change (improvement or worsening) in control of blood sugar levels can disturb vision. If you have proliferative retinopathy (an eye disease associated with diabetes), a very low blood sugar attack may cause temporary loss of vision.
- Swelling of the calves and ankles, caused by temporary build-up of water in the body.

Very rare side effects (may affect up to 1 in 10000 people):

- Change in taste.
- Muscular pain.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or via the link: <https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Before first use:

Store in a refrigerator (between 2°C-8°C). Do not freeze and do not place close to the freezer compartment or a freezer pack. Keep the pens in the box in order to protect from light.

After first use/taking out of the refrigerator:

Do not store the pen in the refrigerator. A pen in use or carried as a spare pen may be stored for up to 6 weeks at a temperature below 30°C and kept away from direct heat or light. Discard the pen after this time period. Do not leave the insulin in the car or in an exceptionally hot or cold place. When the pen is not in use, close the cap to protect it from light.

It is recommended to write the date of start of use/removal from the refrigerator on the product's label.

Do not store different medications in the same package.

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

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Glycerol (85%), m-cresol, zinc chloride, hydrochloric acid, sodium hydroxide, water for injections.

What the medicine looks like and the contents of the package:

A pack of 3 pens. Each pen contains 3 ml (900 units) of a clear and colorless injection solution. Not all pack sizes may be marketed.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

License Holder, Importer and its address: sanofi-aventis Israel Ltd., 10 Beni Gaon Street, Netanya.

Revised in August 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155-31-34440

HYPERGLYCEMIA AND HYPOGLYCEMIA

If you use insulin, always have at least 20 grams of sugar with you, in addition to information identifying you as a diabetic.

HYPERGLYCEMIA (high blood sugar levels)

If your blood sugar level is too high (hyperglycemia), you may not have injected enough insulin.

Why does hyperglycemia occur?

Examples include:

- you did not inject insulin or did not inject enough.
- the insulin became less effective, for example, due to incorrect storage.
- your insulin pen does not work properly.
- you are performing less physical activity than usual.
- you are under stress (emotional distress, excitement).
- you have been injured, underwent surgery, have an inflammation or fever.
- you are taking or have taken certain other medicines (see section 2 "Other medicines and Toujeo").

Warning signs of hyperglycemia

Thirst, increased need to urinate, tiredness, dry skin, redness of the face, loss of appetite, low blood pressure, fast heartbeat, presence of glucose and ketone bodies in the urine. Stomach pain, fast and deep breathing, feeling sleepy or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

What should you do if you experience hyperglycemia?

- Check your blood sugar level and your urine for presence of ketones as soon as any of the above symptoms occur.
- Refer to a doctor immediately if you experience severe hyperglycemia or ketoacidosis; these must always be treated by a doctor, usually in a hospital.

HYPOGLYCEMIA (low blood sugar levels)

If your blood sugar level drops too low, you may lose consciousness. Severe hypoglycemia may cause heart attack or brain damage and may be life-threatening. You must learn to identify when your blood sugar level has dropped too low, so you will be able to take action to prevent it from getting worse.

Why does hypoglycemia occur?

Examples include:

- you inject too much insulin,
- you miss meals or delay meal times,
- you do not eat enough or eat food containing less sugar (carbohydrate) than normal (sugar and substances similar to sugar are called carbohydrates; however, artificial sweeteners are not carbohydrates),
- you lose carbohydrates due to vomiting or diarrhea,
- you drink alcohol, especially if you do not eat much,
- you perform more physical activity than usual or a different type of physical activity,
- you are recovering from an injury or surgery or other stress,
- you are recovering from an illness or from fever,
- you are taking or have stopped taking certain other medicines (see section 2, "Other medicines and Toujeo").

Hypoglycemia is also more likely to occur if:

- you have just started treatment with insulin or you have changed the type of insulin – if low blood sugar occurs, it may be more likely to happen in the morning,
- your blood sugar levels are almost regular or are unstable,
- you changed the area of skin where you inject insulin (for example, from the thigh to the upper arm),
- you suffer from severe kidney or liver disease, or some other disease, such as hypothyroidism.

Warning signs of hypoglycemia

The first signs can generally occur in your body. Examples of symptoms that indicate that your blood sugar level is falling too much or too fast: sweating, clammy skin, anxiety, fast or irregular heartbeats, high blood pressure, and palpitations. These symptoms often occur before the symptoms of low sugar level in the brain.

Signs in your brain include: headaches, intense hunger, nausea, vomiting, tiredness, sleepiness, restlessness, sleep disturbances, aggressive behavior, difficulty concentrating, slow reactions, depression, confusion, speech disturbances (sometimes loss of ability to speak), vision disorders, trembling, inability to move (paralysis), tingling sensation in the hands and legs, numbness and tingling in the mouth area, dizziness, loss of self control, inability to care for yourself, fits and loss of consciousness.

When the signs of hypoglycaemia may be less clear:

The first warning signs of hypoglycemia may change, be weaker or may not occur at all if:

- you are elderly.
- you have had diabetes for a long time.
- you suffer from a certain type of nervous disease (diabetic autonomic neuropathy).
- you have recently had too low blood sugar (e.g., the day before).
- your drop in sugar level develops slowly.
- your low blood sugar is always around "normal" or your blood sugar has gotten much better.
- you have recently changed from an animal-derived insulin to a human insulin such as Toujeo.
- you are taking or have taken certain other medicines (see section 2, "Other medicines and Toujeo").

In such cases, you may develop severe hypoglycemia (and even lose consciousness) when you are aware of the problem. Be familiar with your warning signs.

If necessary, more frequent sugar level tests can help identify mild hypoglycemic events. If you are not sure about your warning signs, avoid situations (e.g., driving a car) in which you or others will be at risk due to hypoglycemia.

What should you do if you experience hypoglycemia?

1. Do not inject insulin. Immediately take approximately 10 to 20 grams of sugar, such as glucose, sugar cubes or a sugar-sweetened drink. Do not drink or eat foods with artificial sweeteners (such as diet drinks); they will not help treat hypoglycemia.
2. Then eat something that has a long-acting effect on raising your blood sugar level (e.g., bread or pasta). Consult the doctor or nurse if you are uncertain about which food you should eat. Recovery from hypoglycemia may be delayed because Toujeo is long-acting.
3. If the hypoglycemia recurs, take another 10 to 20 grams of sugar.
4. Speak with your doctor immediately if you are unable to control the hypoglycemia or if it recurs.

What should others do if you experience hypoglycemia?

Tell your relatives, friends and work colleagues to call for medical help immediately if you cannot swallow or if you lose consciousness. You will need an injection of glucose or glucagon (a medicine which increases the blood sugar level). These injections should be given even if it is not certain that you have hypoglycemia.

Check your blood sugar level immediately after taking glucose, to check that you really have hypoglycemia.

INSTRUCTIONS FOR USE Toujeo solution for injection 300 units/ml in a pre-filled DoubleStar pen

Read this first

Toujeo DoubleStar contains 300 units/ml insulin glargine in a pre-filled pen (which must be discarded after use) containing 3 ml.

- Never re-use needles. If you do, you might get a smaller dose than required or get an overdose, as the needle may be blocked.
- Never 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 on your Toujeo DoubleStar pen is set to 2-unit intervals.

IMPORTANT INFORMATION

- Never share the pen – it is only for you.
- Never use the pen if it is damaged or if you are not sure that it is working properly.
- Always perform a safety test before you use a new pen for the first time, until you see insulin coming out of the tip of the needle (see Step 3). If you see insulin coming out of the tip of the needle, the pen is ready for use. If you do not see insulin coming out before you take your dose, you may get too small a dose or may not get insulin at all. This may cause a high blood sugar level.
- To verify that the pen and needle are all right, always perform a safety test before each injection until you see insulin coming out of the tip of the needle (see Step 3). If you do not perform the safety test before each injection, you may get too little insulin.
- Always carry a spare pen and spare needles in case they get lost or stop working.

Learn to inject

- Before using the pen, talk with the doctor, pharmacist or nurse about how to inject properly.
- This pen is not recommended for use by people who are blind or vision-impaired who are not assisted by a person who has been trained to use the preparation properly.
- Read all of the instructions before using the pen. If you do not follow all of these instructions, you may get too much or too little insulin.

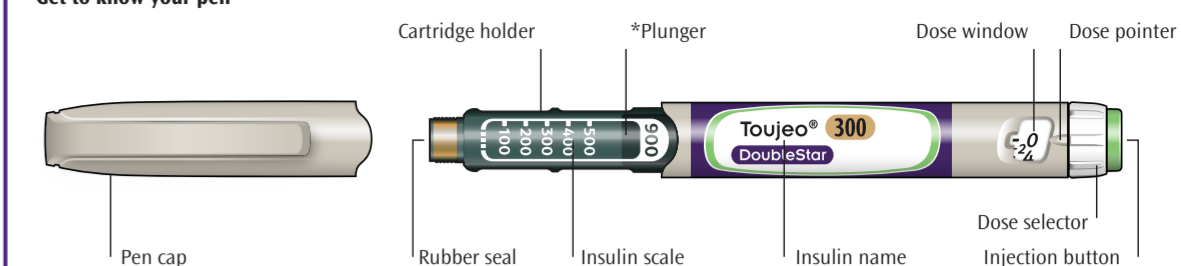
Need help?

If you have any questions about the pen or about diabetes, ask the doctor, pharmacist or nurse.

Additional items you will need

- a new sterile needle (see Step 2).
- a puncture-resistant container for used needles and pens.

Get to know your pen



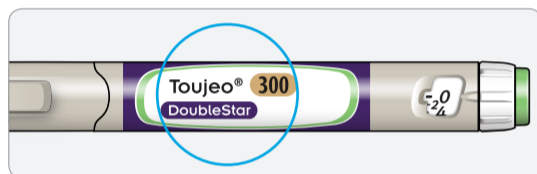
* You will not see the plunger before injecting several doses

Use by	How to store the pen	How to care for your pen	Throwing your pen away
<ul style="list-style-type: none"> Use your pen for up to 6 weeks after the first use. 	<p>Before first use</p> <ul style="list-style-type: none"> Store new pens in a refrigerator, between 2°C and 8°C. Do not freeze. <p>After first use</p> <ul style="list-style-type: none"> Keep your pen at room temperature, below 30°C. Never put your pen back in the refrigerator. Never store your pen with the needle attached to it. 	<p>Handle your pen with care</p> <ul style="list-style-type: none"> Do not drop your pen or knock it against hard surfaces. If you think that your pen has been damaged, do not try to repair it; use a new one. <p>Protect your pen from dust and dirt</p> <ul style="list-style-type: none"> You can clean the outside of your pen by wiping it with a damp cloth. Do not soak, wash or lubricate your pen – this may damage it. 	<ul style="list-style-type: none"> Remove the needle before throwing the pen away. Throw away your used pen as you have been instructed by the pharmacist.

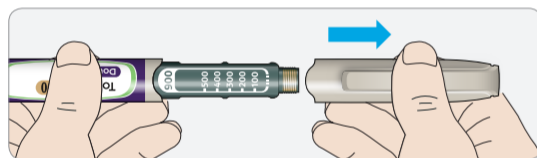
STEP 1: Check your pen

- Take a new pen out of the refrigerator at least one hour before injection. Cold insulin hurts more during the injection.

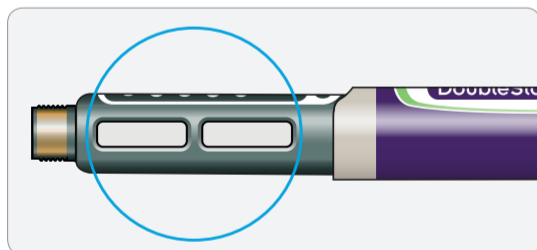
- A Check the name and expiration date on the label of the pen.**
- Make sure you have the correct insulin. This is especially important if you have other injector pens.
 - Never use the pen after the expiration date.



- B Take off the pen cap.**



- C Check that the insulin is clear.**
- Do not use the pen if the insulin looks cloudy, colored or contains particles.



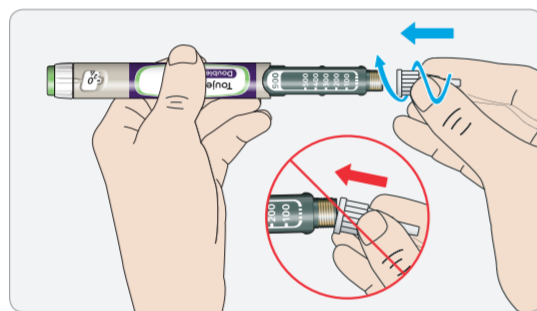
STEP 2 - Attach a new needle

- Always use a new sterile needle for each injection. This helps prevent blockage of needles, contamination of the preparation or infection in the patient.
- Only use needles that are compatible for use with Toujeo DoubleStar (e.g., needles from the companies Artsana, Ypsomed, BD or Owen Mumford), that are 8 mm long or shorter.

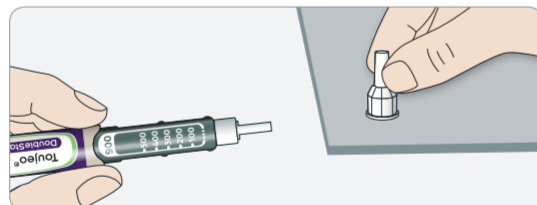
- A Take a new needle and peel off its protective seal.**



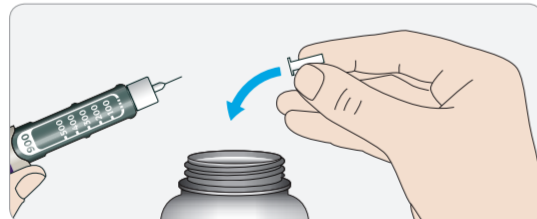
- B Keep the needle straight opposite the pen and screw it onto the pen until fixed. Do not overtighten.**



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



- D Pull off the inner needle cap and throw away.**



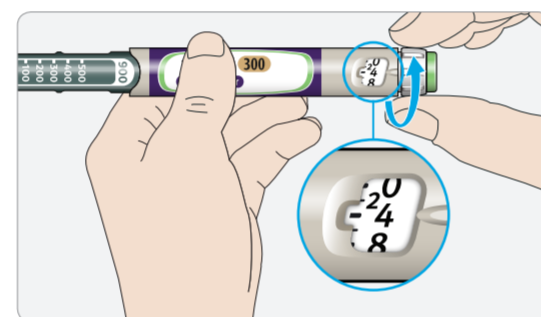
Handling needles

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

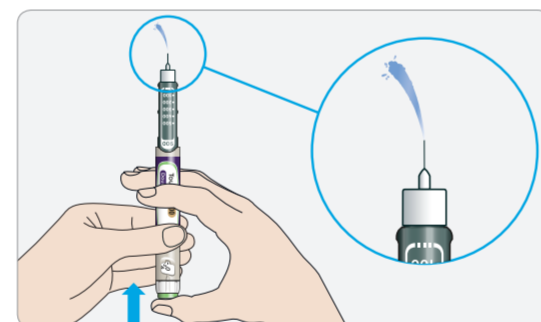
STEP 3 - Do a safety test

- Always do a safety test before each injection. This is to:
 - Check that your pen and the needle are working properly.
 - Make sure that you get the correct insulin dose.
- If the pen is new, perform a safety test before you use it for the first time, until you see insulin coming out of the tip of the needle. If you see insulin coming out of the tip of the needle, the pen is ready for use. If you do not see insulin coming out before you take a dose, you may get too small a dose or may not get insulin at all. This can cause high blood sugar level.

- A Select 4 units by turning the dose selector until the dose pointer points to 4.**



- B Press the injection button all the way in.**
When insulin comes out of the needle tip, your pen is working properly.



- C Repeat this step if no insulin appears:**
- If you are using a new pen for the first time, you may need to repeat this step up to 6 times before seeing insulin.
 - Do not use your pen if there is still no insulin coming out of the tip of the needle. Use a new pen.
 - For all injections, if no insulin comes out, the needle may be blocked. If this happens:
 - change the needle (see Step 6 and Step 2).
 - then repeat the safety test (STEP 3A and 3B).
 - Do not use your pen if there is still no insulin coming out of the needle tip. Use a new pen.
 - Never use a syringe to remove insulin from your pen.

If you see air bubbles

- You may see air bubbles in the insulin. This is normal; they will not harm you.

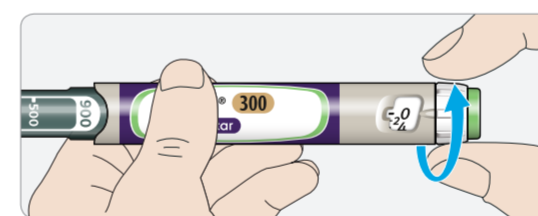
STEP 4 - Select the dose

- Never select a dose or press the injection button without a needle attached. This may damage the pen.
- Toujeo DoubleStar is meant to supply the number of insulin units prescribed by the doctor to you. Do not recalculate for each dose.

- A Make sure a needle is attached and that the dose is set to "0".**



- B Turn the dose selector until the dose pointer lines up with your dose.**
- Set the dose by turning the dose selector to the line in the dose window. Each line equals 2 units.
 - The dial clicks as you turn it.
 - Do not set your dose by counting "clicks". You may set the wrong dose. This may cause you to get too much insulin or not enough insulin.
 - Always check the number in the dose window to confirm that you selected the correct dose.
 - If you turned past your dose, you can turn back again.
 - If there is not enough insulin doses left in your pen for your dose, the dose selector will stop at the number of units left.
 - If you cannot select your full dose, split the dose into two 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 is set to 2-unit intervals. Each line in the dose window represents an even number.



60 units selected



58 units selected

Units of insulin in your pen

- Your pen contains 900 units of insulin. You can select doses from 2 to 160 units in steps of 2 units each time. Each pen contains more than one dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

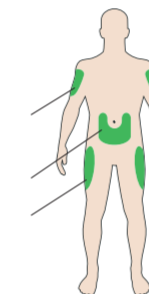
STEP 5 - Inject your dose

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

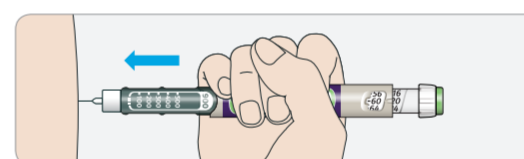
- A Choose an injection site as shown in the picture.**

Injection sites

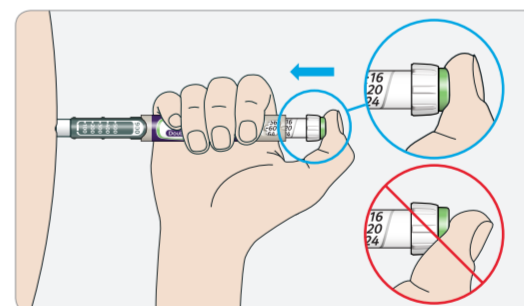
Upper arms
Abdomen
Thighs



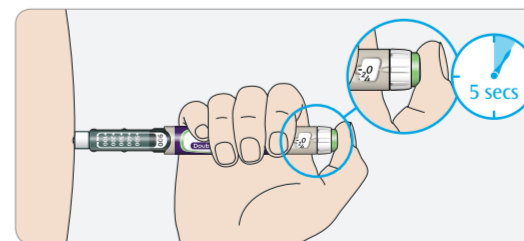
- B Push the needle into your skin as shown by your doctor, pharmacist or nurse.**
- Do not touch the injection button yet.



- C 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.



- 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.



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

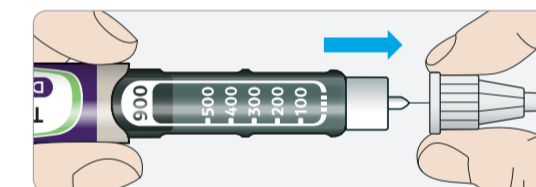
If you find it hard to press the button in:

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

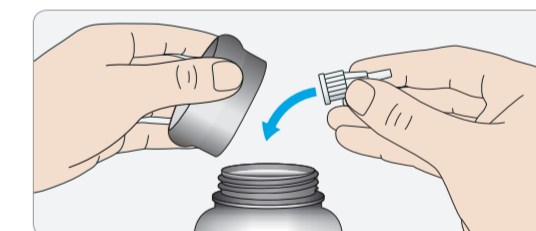
STEP 6 - Remove the needle

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

- A Put the outer needle cap back on the needle, and use it to take the needle off the pen.**
- To reduce the risk of needle injury, never replace the inner needle cap.
 - If your injection is given by another person, or if you are giving an injection to another person, special caution must be taken by the other person when removing and disposing of the needle.
 - Follow recommended safety measures for removal and disposal of needles (contact your medical staff) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.



- B Throw away the used needle in a puncture-resistant container, or as instructed by the pharmacist.**



- C Put the pen cap back on.**
- Do not put the pen back in the refrigerator.

