

Toujeo® 300 units/ml DoubleStar® solution for injection in a pre-filled pen

(insulin glargine)

Each DoubleStar® pen delivers 2-160 units in steps of 2 units

Toujeo DoubleStar® 300 units/ml DoubleStar® solution for injection in a pre-filled pen

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This product is called Toujeo 300 units/ml DoubleStar solution for injection in a pre-filled pen but will be referred to as Toujeo throughout the leaflet.

Toujeo DoubleStar® 300 units/ml DoubleStar® solution for injection in a pre-filled pen

What is in this leaflet

- What Toujeo is and what it is used for
- What you need to know before you use Toujeo
- How to use Toujeo
- Possible side effects
- How to store Toujeo
- Contents of the pack and other information

1. What Toujeo is and what it is used for

Toujeo contains insulin called “insulin glargine”. This is a modified insulin, very similar to human insulin.

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

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

Toujeo lowers your blood sugar steadily over a long period of time. It is used for once daily dosing. You can change the time of your injection if you need to. This is because this medicine lowers your blood sugar over a long period of time (for more information, see section 3).

2. What you need to know before you use Toujeo

Do not use Toujeo

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

Warnings and precautions

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

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

Be especially aware of the following:

- Too low blood sugar (hypoglycaemia). If your blood sugar is too low, follow the guidance for hypoglycaemia (see information in the box at the end of this leaflet).
- If you switch from another type, brand or manufacturer of insulin your insulin dose may need to be changed.
- Pioglitazone. See “Pioglitazone used together with insulin”.
- Ensure to use the right insulin. Medication errors due to mix-up between insulins, particularly between long-acting insulins and rapid-acting insulins have been reported. You must always check the insulin label before each injection to avoid mix-ups between Toujeo and other insulins.
- Never use a syringe to remove Toujeo from your DoubleStar pen. This is to avoid dosing errors and potential overdose which may lead to low blood sugar. Please, see also 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 the Instructions for use). Please, see also section 3.
- If you are blind or have poor eyesight, do not use the pre-filled pen without help. This is because you will not be able to read the dose window on the pen. Get help from a person with good eyesight who is trained in using the pen.

Skin changes at the injection site

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see How to use Toujeo). Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Illnesses and injuries

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

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

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

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

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

Travel

Talk to your doctor before travelling.

You may need to talk about:

- If your type of insulin is available in the country you are visiting.
- How to arrange the supply of insulin, needles and other items.
- How to correctly store your insulin while travelling.
- The time you eat meals and use your insulin.
- The possible effects of changing to different time zones.
- Any health risks in the countries you will visit.
- What you should do in an emergency situation if you feel unwell or become ill.

Children and adolescents

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

Other medicines and 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 (hypoglycaemia) if you take:

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

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

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

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

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

Beta-blockers

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

Pioglitazone used together with insulin

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

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

Toujeo with alcohol

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. Your insulin dose may need to be changed during pregnancy and after giving birth. For the health of your baby, it is particularly important to carefully control your diabetes and to prevent hypoglycaemia. If you are breast-feeding, talk to your doctor, as your insulin doses and your diet might need to be changed.

Driving and using machines

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

Ask your doctor whether you can drive if:

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

Important information about some of the ingredients of Toujeo

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

3. How to use Toujeo

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

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

How much to use

The Toujeo DoubleStar pre-filled pen can provide a dose of 2 to 160 units per injection, in steps 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 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.

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

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

Many factors may affect your blood sugar level. You should know these factors so that you can take the right action if your blood sugar level changes and help stop it becoming too high or too low. See the box at the end of this leaflet for more information.

Flexibility in time of administration

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

Use in elderly patients (65 years and over)

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

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

Before injecting Toujeo

- Read the Instructions for Use that come with this package leaflet.
- If you do not follow all of these instructions, you may get too much or too little insulin.
- Perform a safety test as described in Step 3 of the Instructions for Use. If you don’t, your full dose will not be delivered. If this occurs, you should increase the frequency of checking your blood sugar level and might need to administer additional insulin. Please, also see section 2.

How to inject

- Toujeo is injected under the skin (subcutaneous use or “SC”).
- Inject it into the front of your thighs, upper arms or the front of your waist (abdomen).
- Change the place within the area you inject each day. This will reduce the risk of skin shrinking or thickening (for more information, see “Other side effects” in section 4).

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

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

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

Do not use Toujeo

- In a vein. This will change the way it works and may cause your blood sugar to become too low.
- In an insulin infusion pump.
- If there are particles in the insulin. The solution should be clear, colourless and water-like.

Never use a syringe to remove Toujeo from your DoubleStar pen or severe overdose can result. Please, see also section 2.

If the DoubleStar pen is damaged, has not been stored correctly, if you are not sure that it is working properly or you notice that your blood sugar control is unexpectedly getting worse:

- Throw the pen away and use a new one.
- Talk to your doctor, pharmacist or nurse if you think you have problem with your pen.

If you use more Toujeo than you should
If you have injected too much of this medicine, your blood sugar level may become too low. Check your blood sugar and eat more food to prevent your blood sugar getting too low. If your blood sugar gets too low, see the advice in the box at the end of this leaflet.

If you forget to use Toujeo

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

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

- Do not inject a double dose to make up for a forgotten dose.
- Check your blood sugar and then inject your next dose at the usual time.
- For information on the treatment of hyperglycaemia, see the box at the end of this leaflet.

If you stop using Toujeo

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

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

4. Possible side effects

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

If you notice signs of your blood sugar being too low (hypoglycaemia), take action to increase your blood sugar level straight away (see the box at the end of this leaflet).

- Hypoglycaemia can be very serious and is very common with insulin treatment (may affect more than 1 in 10 people).
- Low blood sugar means that there is not enough sugar in your blood.
- If your blood sugar falls too low, you may pass out (become unconscious).

- Serious low blood sugar may cause brain damage and may be life-threatening.
- For more information, see the box at the end of this leaflet.

Severe allergic reactions (rare, may affect up to 1 in 10,000 people). The signs may include rash and itching all over the body, swelling of skin or mouth, shortness of breath, feeling faint (a fall in blood pressure) with fast heartbeat and sweating. Severe allergic reactions may become life-threatening. Tell a doctor straight away if you notice signs of a severe allergic reaction.

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

- Skin changes at the injection site:** If you inject insulin too often at the same place, the skin may either shrink (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 be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into lumpy areas. Change the injection site with each injection to help prevent these skin changes.

Common: may affect up to 1 in 10 people

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

Rare: may affect up to 1 in 1,000 people

- Eye reactions: A big change in your blood sugar control (getting better or worse) can disturb your vision. If you have an eye disorder related to diabetes called “proliferative retinopathy”, very low blood sugar attack may cause temporary loss of vision.
- Swelling in the calves and ankles, caused by temporary build-up of water in the body.

Very rare: may affect up to 1 in 10,000 people

- Changes in taste (dysgeusia).
- Muscular pain (myalgia).

Tell your doctor, pharmacist or nurse if you notice any of the side effects above.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide moreinformation on the safety of this medicine.

5. How to store Toujeo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the label of the pen after “EXP”. The expiry date refers to the last day of that month.

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

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

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

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Toujeo contains

- The active substance is insulin glargine. Each ml of the solution contains 300 units of insulin glargine (equivalent to 10.91 mg). Each DoubleStar pen contains 3 ml of solution for injection, equivalent to 900 units.

- The other ingredients are: zinc chloride, metacresol, glycerol, water for injections, and sodium hydroxide (see section 2 “Important information about some of the ingredients of Toujeo”) and hydrochloric acid (for pH adjustment).

What Toujeo looks like and contents of the pack
Toujeo is a clear and colourless solution. Each DoubleStar pen contains 3 ml of solution for injection (equivalent to 900 units). Pack of 3 pre-filled pens. Not all pack sizes may be marketed.

Manufacturer:
Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
Brüningstraße 50
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Germany

Procured from within the EU and repackaged for the PL Holder:
Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

PL 45763/1272

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For any information about this medicine, please contact the local representative of the Product Licence Holder:
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email: MedInfo@abacusmedicine.co.uk or
drugsafetyuk@abacusmedicine.co.uk

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Blind or partially sighted? Is this leaflet hard to see or read? Call 02036301310 or write to info@abacusmedicine.com to obtain the leaflet in a format suitable for you.

HYPERGLYCAEMIA AND HYPOGLYCAEMIA

If you take insulin, you should always carry the following things with you:

- Sugar (at least 20 grams).
- Information so that others know you have diabetes.

Hyperglycaemia (high blood sugar levels)

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

Reasons why hyperglycaemia may happen:
Examples include:

- You have not injected your insulin or not injected enough.
- Your insulin has become less effective – for example because it was not stored properly.
- Your insulin pen does not work properly.
- You are doing less exercise than usual.
- You are under stress – such as emotional distress or excitement.
- You have an injury, infection or fever or have had an operation.
- You are taking or have taken certain other medicines (see section 2, “Other medicines and Toujeo”).

Warning signs of hyperglycaemia
Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heart beat, and glucose and ketone bodies in urine. Stomach pain, fast and deep breathing, feeling sleepy or passing out (becoming unconscious) may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

What to do if you experience hyperglycaemia

- 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 hyperglycaemia or ketoacidosis. This must always be treated by a doctor, normally in a hospital.

Hypoglycaemia (low blood sugar levels)

If your blood sugar level falls too much you may pass out (become unconscious). Serious hypoglycaemia may cause a heart attack or brain damage and may be life-threatening. You should learn to recognise the signs when your blood sugar is falling – so you can take action to stop it getting worse.

Reasons why hypoglycaemia may happen:

Examples include:

- You inject too much insulin.
- You miss meals or delay them.
- You do not eat enough, or eat food containing less sugar (carbohydrate) than normal – artificial sweeteners are not carbohydrates.
- You drink alcohol – especially when you have not eaten much.
- You lose carbohydrates from being sick (vomiting) or diarrhoea.
- You are doing more exercise than usual or a different type of physical activity.
- You are recovering from an injury, operation 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").

Hypoglycaemia is also more likely to happen if:

- You have just started insulin treatment or changed to another insulin – if low blood sugar occurs, it may be more likely to happen in the morning.
- Your blood sugar levels are almost normal or are unstable.
- You change the area of skin where you inject insulin. For example from the thigh to the upper arm.
- You have severe kidney or liver disease, or some other disease such as hypothyroidism.

Warning signs of hypoglycaemia

The first signs may be in your body generally. Examples of signs that your blood sugar level is falling too much or too fast include: sweating, clammy skin, feeling anxious, fast or irregular heart beat, high blood pressure and palpitations. These signs often develop before the signs of a low sugar level in the brain.

Signs in your brain include: headaches, feeling very hungry, feeling sick (nausea) or being sick (vomiting), feeling tired, sleepy, restless, sleeping problems, aggressive behaviour, difficulty concentrating, slow reactions, depression, feeling confused, difficulty speaking (sometimes total loss of speech), changes in your sight, trembling, being unable to move (paralysis), tingling in the hands or arms, feeling numb and tingling often around the mouth, feeling dizzy, loss of self-control, being unable to look after yourself, fits, passing out.

When the signs of hypoglycaemia may be less clear: The first warning signs of hypoglycaemia may change, be weaker or missing altogether if:

- You are elderly.
- You have had diabetes for a long time.
- You have a certain type of nervous disease (called "diabetic autonomic neuropathy").
- You have recently had too low blood sugar (for example the day before).
- Your low blood sugar comes on slowly.
- Your low blood sugar is always around "normal" or your blood sugar has got much better.
- You have recently changed from an animal insulin to a human insulin, like Toujeo.
- You are taking or have taken certain other medicines (see section 2, "Other medicines and Toujeo").

In such cases, you may develop severe hypoglycaemia (and even pass out) before you know what is happening. Be familiar with your warning signs. If necessary, you might need to test your blood sugar more often. This can help to spot mild hypoglycaemic episodes. If you find it difficult to recognise your warning signs, you should avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

What to do if you experience hypoglycaemia?

- 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.
- Then 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.
- If the hypoglycaemia comes back again, take another 10 to 20 grams of sugar.
- Speak to a doctor straight away if you are not able to control the hypoglycaemia, or it comes back again.

What other people should do if you have hypoglycaemia

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 will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections should be given even if it is not certain that you have hypoglycaemia.

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

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

Read this first

Toujeo DoubleStar contains 300 units/ml insulin glargine in a 3 ml disposable pre-filled pen

- Never re-use needles.** If you do you might not get your dose (underdosing) or get too much (overdosing) as the needle could block.
- 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 of your Toujeo DoubleStar pen dials in steps of **2 units**.

Important information

- Never share your pen** – it is only for you.
- Never use your 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 needle tip** (see STEP 3). 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.
- To ensure the pen and needle are working, always perform the safety test until you see insulin coming out of the needle tip before each injection** (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

- Talk with your doctor, pharmacist or nurse about how to inject, before using your pen.
- This pen is not recommended for use by people who are blind or have visual impairments without the assistance of a person trained in the proper use of the product.
- 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.

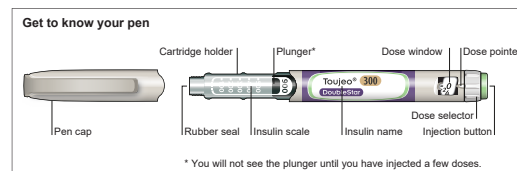
Need help?

If you have any questions about your pen or about diabetes, ask your doctor, pharmacist or nurse or call the Sanofi number on the front of this leaflet.

Extra 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



Use by

- Only use your pen for up to 6 weeks after its first use.

How to store your pen

Before first use

- Keep new pens in a fridge, at 2 °C to 8 °C.
- Do not freeze.

After first use

- Keep your pen at room temperature, **below 30 °C**.
- Never put your pen back in the fridge.
- Never store your pen with the needle attached.
- Store your pen with the pen cap on.
- Keep your pen and needles out of the sight and 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 repair 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.
- 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 your used pen as told by your pharmacist or local authority.

STEP 1: Check your pen

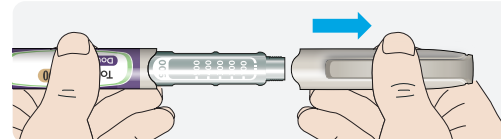
- Take a new pen out of the fridge at least 1 hour before you inject. Cold insulin is more painful to inject.

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

- Make sure you have the correct insulin. This is especially important if you have other injector pens.
- Never use your pen after the expiration date.

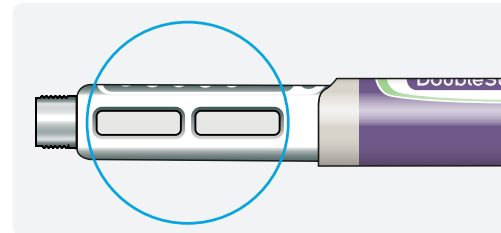


B Pull off the pen cap.



C Check that the insulin is clear.

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



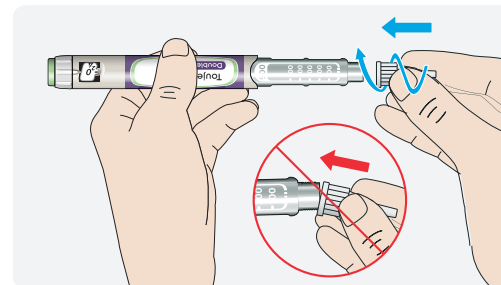
STEP 2: Attach a new needle

- Always use a new sterile needle** for each injection. This helps stop blocked needles, contamination and infection.
- Only use needles that are compatible for use with Toujeo DoubleStar (e.g. needles from BD, Ypsomed, Artsana or Owen Mumford) that are 8 mm long or shorter.

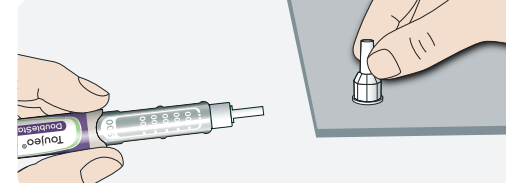
A Take a new needle and peel off the protective seal.



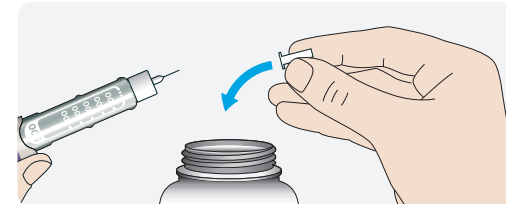
B Keep the needle straight and screw it onto the pen until fixed. Do not overtighten.



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



D Pull off the inner needle cap and throw away.



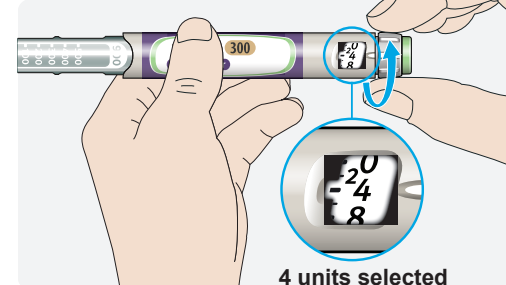
Handling needles

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

STEP 3: Do a safety test

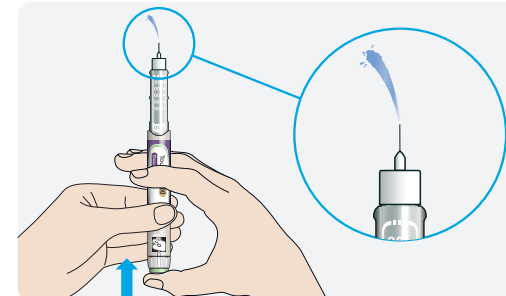
- Always do a safety test before each injection** – this is to:
 - check your pen and the needle are working properly.
 - make sure that you get the correct insulin dose.
- If the pen is new, you must perform safety tests before you use the pen for the first time until you see insulin coming out of the 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.

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



B Press the injection button all the way in.

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



C Repeat this step if no insulin appears:

- If you are using a new pen for the first time, you may have 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 needle tip. 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 STEP 3 B).
 - 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

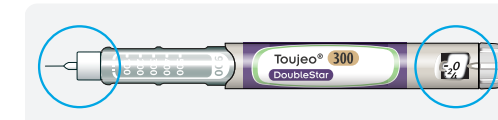
- You may see air bubbles in the insulin. This is normal, they will not harm you.

STEP 4: Select the dose

- Never select a dose or press the injection button without a needle attached.** This may damage your pen.

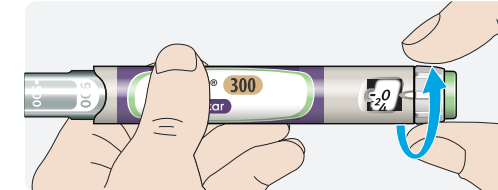
Toujeo DoubleStar is made to deliver the number of insulin units that your doctor prescribed. Do not perform any dose re-calculation.

A Make sure a needle is attached and 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 a line in the dose window. Each line equals 2 units.
- The dial clicks as you turn it.
- 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.
- Always check the number in the dose window to make sure you dialled the correct dose.
- 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 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 adjusts in steps of 2 units. Each line in the dose window is an even number:



60 units selected



58 units selected

Units of insulin in your pen

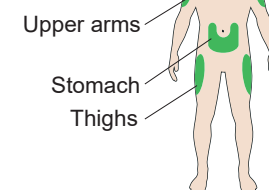
- Your pen contains a total of 900 units of insulin. You can select doses from 2 to 160 units in steps of 2 units at a time. Each pen contains more than one dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

STEP 5: Inject your dose

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

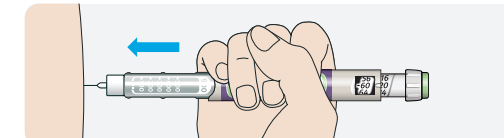
A Choose a place to inject as shown in the picture labelled "Places to inject"

Places to inject



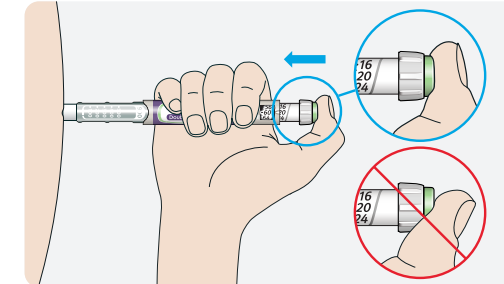
B Push the needle into your skin as shown by your doctor, pharmacist or nurse.

- Do not touch the injection button yet.



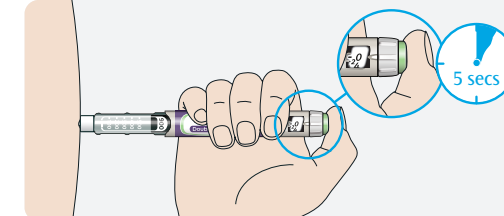
C Place your thumb on the injection button. Then press all the way in and hold.

- 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 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 button in:

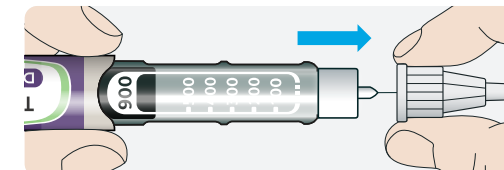
- Change the needle (see STEP 6 and STEP 2) then do a safety test (see STEP 3).
- If you still find it hard to press in, get a new pen.
- Never use a syringe to remove insulin from your pen.

STEP 6: Remove the needle

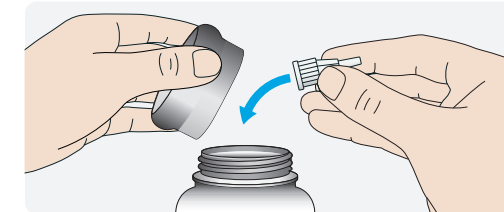
- Take care when handling needles – this is to prevent needle injury and cross-infection.
- Never put the inner needle cap back on.

A Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen.

- To reduce the risk of accidental 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 this person when removing and disposing of the needle.
- Follow recommended safety measures for removal and disposal of needles (contact your doctor, pharmacist or nurse) 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 told by your pharmacist or local authority.



C Put the pen cap back on.

- Do not put the pen back in the fridge.

