



YOUR TOUJEO[®] DOUBLESTAR

(insulin glargine 300 units/mL)

HANDBOOK

GETTING THE MOST FROM YOUR TREATMENT

This item is intended for adults, adolescents and children from the age of 6 years with diabetes who have been prescribed Toujeo[®] with the DoubleStar pen

This item has been developed and funded by Sanofi.

Start your journey with Toujeo

This booklet will support you in making a positive start to managing your diabetes by helping you understand what Toujeo is and why you need it, providing you with a step-by-step guide on how to take it.

It's intended as additional support to the advice from your healthcare professionals and does not replace the patient information leaflet, so please read that leaflet alongside this booklet.

Contents

Get to know Toujeo	3
Your Toujeo DoubleStar pen	4
Things to know before you inject	6
Injecting insulin	8
Adjusting your dose	10
How to adjust your dose	12
Recording your dose adjustments	12
Possible side effects	14
FAQs	16

Your healthcare professional will enter your recommended dose on page 10.

Get to know Toujeo

What is Toujeo?

Toujeo is a **long-acting insulin** called **insulin glargine 300 units/mL**. It comes in a pre-filled disposable pen called Toujeo DoubleStar.

Why have you been prescribed Toujeo?

Toujeo is used to help you manage your diabetes by **steadily lowering your blood sugar levels over 24 hours**.

When should you take Toujeo?

Toujeo should be taken **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 take it.

Other medications and Toujeo

Tell your healthcare professionals if you're taking, have recently taken or might take any other medicines. Some medicines can change your blood sugar levels and this may mean your insulin dose has to change. For the same reason, let them know if you're stopping any medication.

As part of your treatment plan, you may also need to inject a short-acting insulin at mealtimes. If so, it's very important that you don't mix your insulins together, as both Toujeo and short-acting insulin are clear in colour so it's important to make sure you're using the correct insulin in the right pen at each injection.

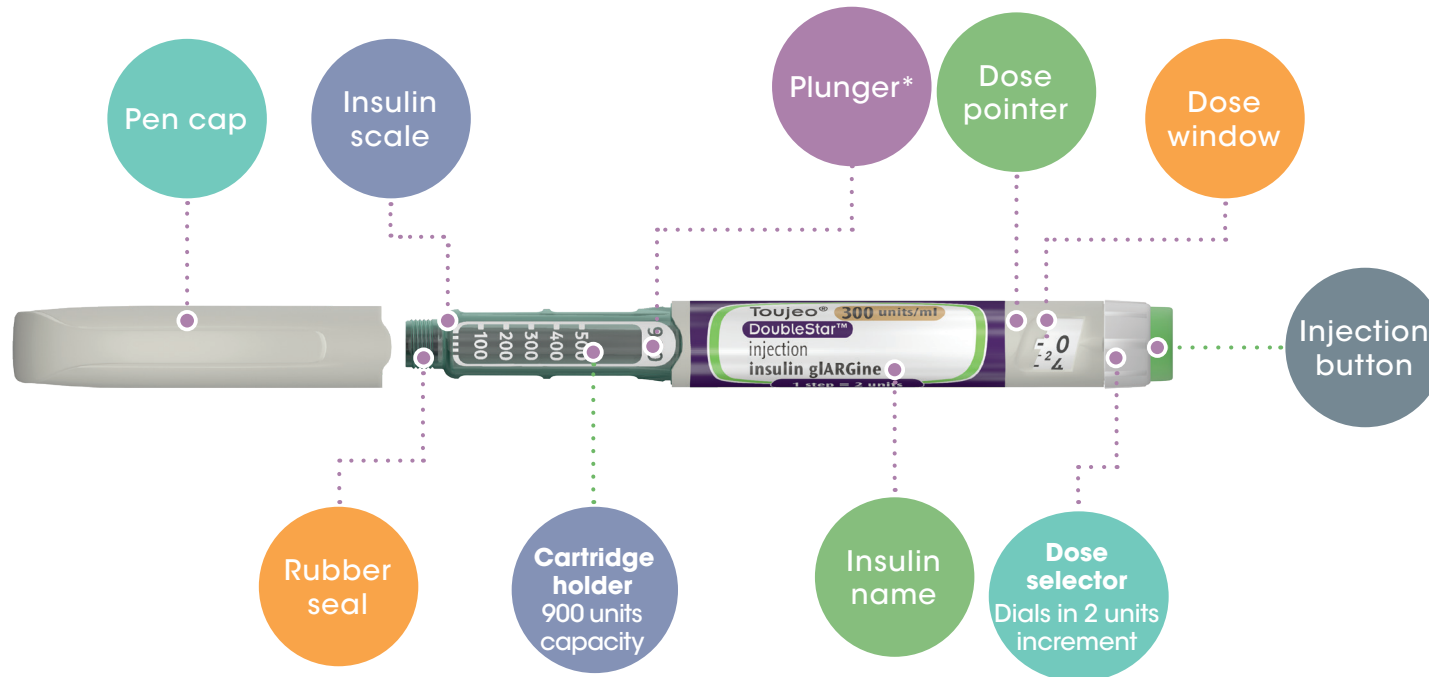
Always take this medicine exactly as your healthcare professional has told you.



Reference 1.

Your Toujeo DoubleStar pen

Before you start using Toujeo DoubleStar, it's a good idea to familiarise yourself with the pen. If you have any questions about the pen, ask your healthcare professionals.



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

How to store your pen:

Before first use:

- Keep your new pen in the outer carton to protect it from light
- Keep your pen in the fridge, between 2°C to 8°C
- Do not freeze
- Remember to remove your pen from the fridge at least 1 hour before use

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 cap on, away from direct heat or light
- Always dispose of used needles in an appropriate sharps bin

Use by:

- Only use your pen for up to 6 weeks after its first use
- Never use your pen after the expiration date

How to throw your pen away:

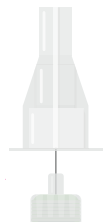
- Remove the needle before throwing your pen away
- Throw away your used pen as advised by your healthcare professional or local authority

Things to know before you inject:

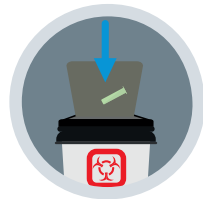
Do's and don'ts:

Do's	Don'ts
✓ Always perform a safety check	✗ Never re-use your needles
✓ Always carry a spare pen and needles in case they get lost or stop working	✗ Never use a syringe to remove insulin from your pen
	✗ Never use your pen if it's damaged
	✗ Never share your pen

Extra items you will need:



A new sterile needle for each injection



A puncture resistant container to throw away used needles and pens

Injecting insulin

Giving yourself an insulin injection isn't difficult, but it does take practice. Your healthcare professionals will show you how.

The 3 recommended injection sites are:

The outer, upper arms:

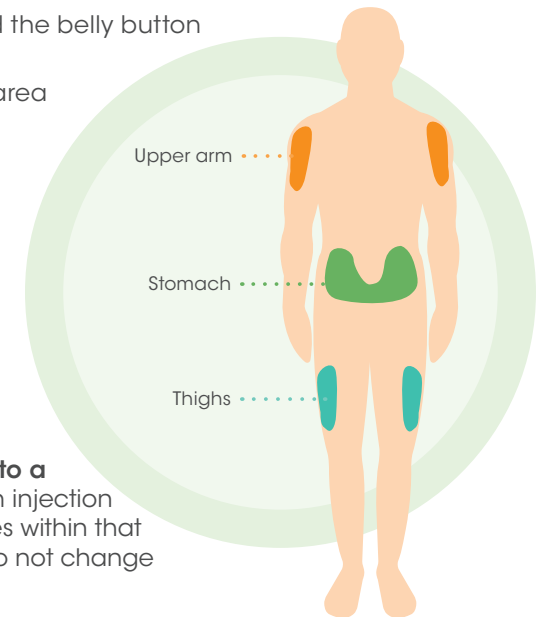
use the outer back area of the upper arm where there is fatty tissue

The stomach:

except for a 2-inch circle around the belly button

The top and outer thighs:

avoid injecting too close to the area above the knee



You should **inject under the skin**, and to prevent damage, **inject into a different site each time**. Select an injection area and rotate your injection sites within that area for approximately a week. Do not change injection areas daily, only sites.

Skin changes at the injection site

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

Injecting insulin

Your healthcare professionals will show you how to inject your insulin, always follow their advice and don't hesitate to ask them any questions. For more detailed information, please also refer to the patient information leaflet.

1 Check your pen



- Ensure you're using the correct insulin
- Check the pen is not damaged
- Check the expiration date has not passed
- Check that the insulin is clear and **DO NOT** use the pen if the insulin looks cloudy or contains particles

2 Attach a new needle



- Take a new needle and peel off the protective seal
- Screw the new needle onto the pen until fixed. **DO NOT** over-tighten
- Remove the outer needle cap. Keep this to use again after your injection
- Pull off the inner needle cap and throw it away

3 Always do a safety test



- Turn the dose selector by 4 units and press the injection button down all the way to ensure insulin comes out of the needle

If no insulin comes out of the needle:

- Repeat the safety test up to 6 times
- Failing this, replace the needle and test it again
- If insulin still doesn't come out, use a new pen

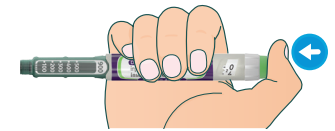
Reference 1.

4 Select the dose



- Ensure the needle is attached and the dose is set to '0'
- Turn the dose selector until the pointer lines up with your intended dose
- If you cannot select your full prescribed dose, split the dose into two injections or use a new pen to make up the remaining amount

5 Inject your dose



- To prevent damage to your skin, inject into a different area each time, swapping between the upper arms, thighs or stomach
- Push the needle into the skin of your chosen injection site and press the injection button all the way down
- When you see '0' in the dose window, slowly count from 1 to 5, to make sure you inject the full dose. You can then release the injection button and remove the needle from your skin

6 Remove the needle



- Place the outer needle cap back onto the pen and turn it several times to remove the needle
- Throw the used needle away in a puncture resistant container
- Place the pen cap back onto the pen and store it at room temperature
- Never take insulin out of the pen with a syringe.

Reference 1.

Adjusting your dose

Please discuss how to adjust your insulin dose with your healthcare professional

Toujeo adjustment rule card

This rule card must be filled in by your healthcare professional. Dose increase and decrease should always be an even number as Toujeo DoubleStar dials by 2 Units.

Your insulin is called Toujeo (insulin glargine 300 units/mL)		
Inject it every day at (hour):	<input type="text"/>	
Your starting dose is:	<input type="text"/>	units
If at ANY time you have hypoglycaemia (hypo) symptoms or a blood sugar reading which is less than:	<input type="text"/>	DECREASE your insulin dose by: <input type="text"/> units
If your middle fasting reading is below:	<input type="text"/>	DECREASE your insulin dose by: <input type="text"/> units
If your middle fasting reading is between:	<input type="text"/> & <input type="text"/>	keep the same dose
If your middle fasting reading is above:	<input type="text"/>	INCREASE your insulin dose by: <input type="text"/> units
If your middle fasting reading is above:	<input type="text"/>	INCREASE your insulin dose by: <input type="text"/> units

For more information on the symptoms and causes of a hypoglycaemia, please refer to **page 14** within this handbook.

Instructions

It can take some time to adjust your insulin dose and find the right one for you. Your dose should be adjusted slowly, so your body can adapt to the changes as your blood sugar control improves. When you find the right dose, it's important for you to stick to it, so you can feel better and have more energy.

To adjust your dose you need to measure your fasting blood sugar levels for 3 consecutive days – your healthcare professionals will suggest the best days for you to do this. After the third reading you should adjust your dose according to your rule card, if required.

Fasting blood sugar levels



The word 'fasting' means **not eating or drinking any liquids other than water for 8 hours**. This is when you should measure the level of sugar in your blood, so you can get your fasting blood sugar level and use it to calculate any dose adjustments.



You should normally test your fasting blood sugar levels **first thing in the morning** when you wake up, before you have any breakfast or anything to drink other than water.

Please discuss how to adjust your insulin dose with your healthcare professional

How to adjust your dose

Use this step-by-step guide to understand how to calculate your dose adjustments if required, and use the next few pages to do so.

Day/date	Day/date	Day/date
Monday 4 th	Tuesday 5 th	Wednesday 6 th
Fasting reading	Fasting reading	Fasting reading
8.6 mmol/L	10.1 mmol/L	9.3 mmol/L

Order your readings from highest to lowest

Highest reading:	10.1
Middle reading:	9.3
Lowest reading:	8.6

Calculate your adjustment using the rule card

Current daily dose	=	Dose adjustment	=	New daily dose
22 units		+4 units		26 units

1

Using your rule card on **page 10**, write down the **starting daily dose** recommended by your healthcare professionals.

2

Take your recommended daily dose at the same time every day. On the 3 consecutive days specified by your healthcare professionals, record your **fasting blood sugar readings** here.

If you have any hypo symptoms or a blood sugar reading less than that shown on the rule card, you must immediately decrease your insulin dose by the amount stated.

3

Once you have fasting readings from your 3 consecutive days, rewrite them, ordering them from **highest to lowest** in these boxes.

4

Use the **middle reading** and your **rule card** to calculate your dose adjustment.

5

Add your **dose adjustment** to your **current daily dose** and calculate your **new daily dose**. Continue to take your new daily dose at the same time every day as instructed.

6

Repeat the test as instructed by your healthcare professionals and adjust your dose again if required, until your middle reading is at your target.

Reference 2.

Possible side effects

Possible side effects include:









- hypoglycaemia
- hyperglycaemia
- skin changes or an allergic reaction at the injection site

What is hypoglycaemia?

Normally your blood sugar levels should be between 4–7 mmol/L when you're fasting (before breakfast) or as individually recommended by your healthcare professional. If your blood sugar levels fall below 4 mmol/L, you may start to feel unwell, this is known as hypoglycaemia or a 'hypo'.

Signs of a hypo

A hypo can occur quickly so it's important to **know the early warning signs**. The most common ones are:

- | | |
|---|--|
|  tiredness or headaches |  sweating heavily |
|  dizziness or shaking |  being sick |
|  rapid heart beat |  blurred vision |
|  feeling hungry |  feeling anxious or excited |

If you experience any of these symptoms you must **act quickly** and take the following steps: have a sugary drink (non-diet), snack or 4–5 glucose tablets; test your blood sugar levels after 10–15 minutes. If it's more than 4 mmol/L eat your main meal (containing carbohydrates) or have a starchy snack, such as a sandwich, a biscuit or fruit. If it's less than 4 mmol/L eat or drink more sugary foods, or take more glucose tablets and test your blood sugar levels again.

Not acting quickly when you have a hypo could lead you to become unconscious. Make sure your relatives, friends and close colleagues know how to react if this happens. They should put you in the recovery position and **call an ambulance immediately**.

References 4 and 5.

What is hyperglycaemia?

Hyperglycaemia or a 'hyper' can occur when your blood sugar levels get too high and increase above 7 mmol/L before a meal, and 8.5 mmol/L 2 hours after a meal.

Signs of a hyper

A hyper can also occur quickly so it's important to **know the early warning signs**. The most common ones are:

- | | |
|--|--|
|  urinating more than usual |  tiredness |
|  feeling thirsty and having a dry mouth |  headache |
|  being sick |  blurred vision |

If you experience symptoms of hyperglycaemia, follow the advice of your healthcare professionals to reduce your blood sugar level. You may be advised to drink plenty of sugar-free fluids (especially if you're dehydrated) and/or to adjust your dose of insulin or diabetes medication.

If you're experiencing severe symptoms such as being sick, rapid heartbeat, irregular breathing or feeling sleepy, you should seek medical assistance immediately.

If you have any questions about side effects, talk to your healthcare professional.

References 6 and 7.

FAQs

What do I do if there are air bubbles in the pen container?

It's normal to have small air bubbles in the pen container and they will not harm you. Your dose will still be correct and you will be able to use the pen as instructed.

Which needle do I need?

Your Toujeo DoubleStar pen can be used with a range of small, disposable needles of different sizes. The needles are small to minimise any discomfort. Your healthcare professionals will choose and prescribe the right size needles for you. Please discuss with your healthcare professional how to dispose of your used needles safely.

What if no insulin comes out during activation?

The needle may be blocked or not screwed on properly. Remove the needle and attach a new one. If there is still no insulin being ejected, your Toujeo DoubleStar may be damaged. If this is the case, do not use the pen.

What do I do if it's hard to press the injection button all the way down?

Withdraw the needle and check that it's screwed on correctly. If it's still difficult to push the injection button, the needle may be blocked, so remove it and attach a new one. If there is still no insulin being ejected, your Toujeo DoubleStar may be damaged. If this is the case, do not use the pen.

What do I do if I accidentally inject myself before my Toujeo DoubleStar pen is activated?

Do not try to correct this by giving yourself a second injection. Contact your healthcare professionals for advice on what to do next and how to check your blood sugar levels.

Do I have to change my needle after each injection?

Yes, never use a needle more than once. This will help prevent infections at the injection site and stop the needle from becoming blocked.

What if I am taking (or intend to take) other medicines at the same time as Toujeo?

Some medicines can change your blood sugar levels. This may mean your insulin dose has to change. So, before taking a medicine ask your healthcare professionals if it will affect your blood sugar levels and what action, if any, you need to take. You also need to be careful when you stop taking a medicine.

What happens if I miss a dose?

Refer to page 3 – Get to know Toujeo

If you miss a dose of Toujeo, you may inject up to three hours after your normal injection time. If that window of time has passed, check your blood sugar levels frequently and then resume your next scheduled dose at your normal injection time.

Contact your healthcare professional for further information.

If you're in any doubt about any of these FAQs, please speak to your healthcare professionals, or call the freephone 24/7 Sanofi Diabetes care-line: 08000 35 25 25.

Notes

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Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at yellowcard.mhra.gov.uk or to Sanofi by phoning **0800 0902314**.

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

Freephone 24-hour Sanofi Diabetes care-line:

08000 35 25 25

Sanofi, 410 Thames Valley Park Drive, Reading Berkshire RG6 1PT

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References:

1. Toujeo® patient information leaflet. Date revised: July 2020.
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3. Diabetes.co.uk. Fasting blood sugar levels. Available at: https://www.diabetes.co.uk/diabetes_care/fasting-blood-sugar-levels.html. Date accessed: October 2020.
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6. Diabetes UK. Hypers. Available at: <https://www.diabetes.org.uk/guide-to-diabetes/complications/hypers>. Date accessed: October 2020.
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