

TOUJEO[®] (INSULIN GLARGINE 300 units/ml)

Toujeo[®] 300 units/ml SoloStar[®], solution for injection in a pre-filled pen
Toujeo[®] 300 units/ml DoubleStar[™], solution for injection in a pre-filled pen

IMPORTANT SAFETY INFORMATION

GUIDE FOR PATIENTS AND/OR CARERS:

- If you are prescribed Toujeo[®] you must be trained on how to use the Toujeo[®] pen by your healthcare professional and you must read the full Instructions For Use leaflet accompanying the pen.
- This document is provided as a guide.
- Start with the dose in units as prescribed by your healthcare professional.

What is Toujeo[®]?

Toujeo[®] is a pre-filled injection pen which contains insulin glargine 300 units per ml. It is a modified insulin, very similar to human insulin. Toujeo[®] lowers your blood sugar steadily over a long period of time. It is used for once daily dosing.

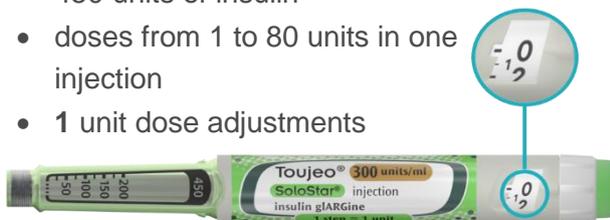
How do I use Toujeo[®]?

- ✓ Start with the dose in units written on your medical prescription.
- ✓ The dose window of the Toujeo[®] pen shows the number of units of Toujeo[®] to be injected.
- ✗ Do not make any dose re-calculation as this will already have been done by your healthcare provider, if required (see below).

Toujeo[®] (insulin glargine 300 units/ml) is available in two different presentations

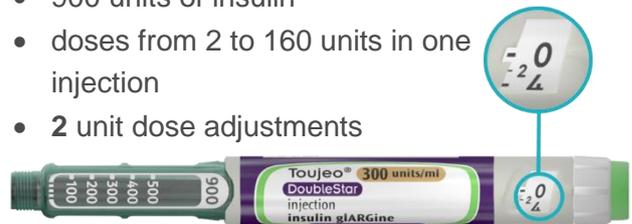
Toujeo[®] SoloStar[®]
(1.5 ml pre-filled pen/450 units)
contains:

- 450 units of insulin
- doses from 1 to 80 units in one injection
- 1 unit dose adjustments



Toujeo[®] DoubleStar[™]
(3 ml pre-filled pen/900 units)
contains:

- 900 units of insulin
- doses from 2 to 160 units in one injection
- 2 unit dose adjustments



The dose increment in
Toujeo[®] SoloStar[®] is 1 unit

The dose delivered is the one shown in the dose window.

The dose increment in
Toujeo[®] DoubleStar[™] is 2 units

The dose delivered is the one shown in the dose window.

How do I switch to or from Toujeo[®]?

Important information during the initial weeks when prescribed Toujeo[®]

- Toujeo[®] (insulin glargine 300 units/ml) and insulin glargine 100 units/ml are **not bioequivalent and are therefore not interchangeable without dose adjustment** (this means the drugs are not the same and you must not switch between them without adjusting the dose).
- The switch from one insulin therapy to another should only be done when prescribed by your healthcare provider. The dose recommended by your healthcare provider should always be followed.
- Your blood glucose needs to be monitored closely during the switch and the initial weeks thereafter.

Before injecting Toujeo[®]

 Read the Instructions for Use that come with the package leaflet.

 If you do not follow all of these instructions, you may get too much or too little insulin leading to a potentially serious hypo or poor control of your diabetes.

Please consult your healthcare professional for further information.

Before injecting Toujeo[®] read the Instructions for Use that come with the package leaflet.

If you get any medication error or 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 any medication error or side effects to:

Sanofi by Telephone: 01 403 5600 or via e-mail: IEPharmacovigilance@sanofi.com

HPRA Pharmacovigilance. Website: www.hpra.ie

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