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 HEALTHCARE PROFESSIONALS

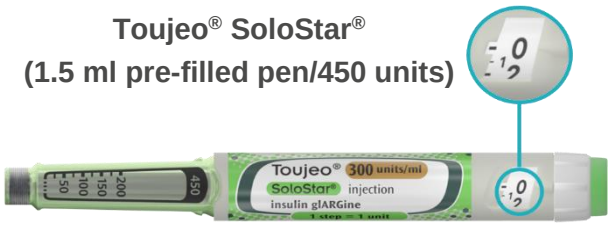
- **This document is supplied as a guide to avoid medication errors. Please refer to the Summary of Product Characteristics before prescribing and dispensing a Toujeo® pen.**
- **Please provide your patients with the Patient Guide prior to prescribing or dispensing Toujeo® for the first time or when switching to a new pen to ensure that your patients and their carers are adequately informed on how to use Toujeo® to help reduce the risk of medication errors.**

The following information must be written on each prescription for Toujeo®

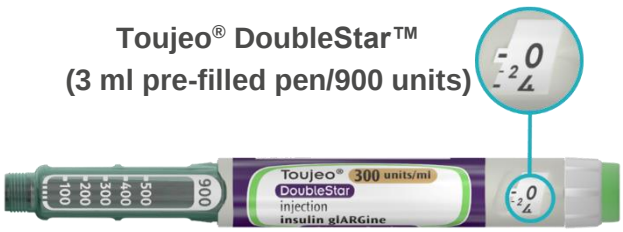
- ✓ Trade name and concentration (Toujeo® SoloStar® 300 units/ml [**or Toujeo® DoubleStar™ 300 units/ml**])
- ✓ Recommended daily dose in units according to the different situations outlined

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

Toujeo® SoloStar®
(1.5 ml pre-filled pen/450 units)



Toujeo® DoubleStar™
(3 ml pre-filled pen/900 units)

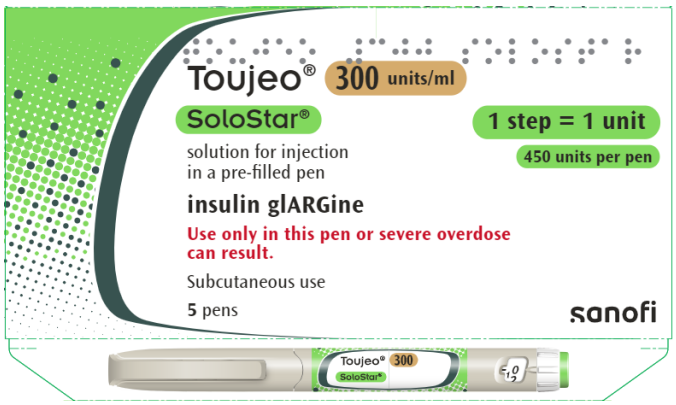


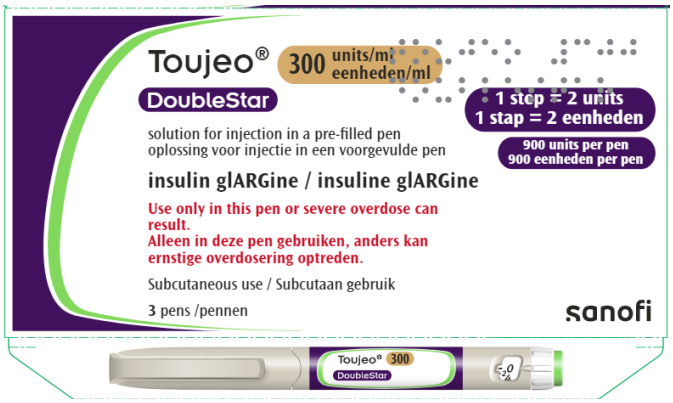
The dose increment in Toujeo® SoloStar® is 1 unit

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.





Key safety elements when switching from or to an insulin with a different strength.

Important information on adjustments during the initial weeks when prescribing Toujeo® (insulin glargine 300 units/ml)

Switch from insulin glargine 100 units/ml to Toujeo® (insulin glargine 300 units/ml)

- **Insulin glargine 100 units/ml and Toujeo® (insulin glargine 300 units/ml) are not bioequivalent and are therefore not interchangeable without dose adjustment.**
- Dose adjustment may be needed when patients are switched to an insulin with a different strength.
- Toujeo® (insulin glargine 300 units/ml) dose regimen (dose and timing) should be adjusted according to individual response to treatment. After titration, on average a 10–18% higher basal insulin dose is needed to achieve target ranges for plasma glucose levels when using Toujeo® 300 units/ml formulation compared to the 100 units/ml formulation.

Switch from other basal insulins to Toujeo® (insulin glargine 300 units/ml)

- When switching from a treatment regimen with an intermediate or long-acting insulin product to a regimen with Toujeo® 300 units/ml, a change in the dose of the basal insulin may be required and the concomitant anti-hyperglycaemic treatment may need to be adjusted. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter.
- **Switching from once-daily basal insulins to once-daily Toujeo® (insulin glargine 300 units/ml)** can be done unit-to-unit based on previous dose.
- **Switching from twice-daily basal insulins to once-daily Toujeo® (insulin glargine 300 units/ml)**, the recommended initial Toujeo® (insulin glargine 300 units/ml) dose is 80% of the total daily dose of basal insulin that is being discontinued.
- Blood glucose monitoring by patients is needed during the switch and the initial weeks thereafter.

Switch from Toujeo® (insulin glargine 300 units/ml) to other basal insulins

- Switching from Toujeo® (insulin glargine 300 units/ml) to insulin glargine 100 units/ml results in an increased risk of hypoglycaemic events, mainly in the first week after the switch.
- To reduce the risk of hypoglycaemia, patients who are changing their basal insulin regimen from an insulin regimen with once daily Toujeo® (insulin glargine 300 units/ml) to a once daily regimen with insulin glargine 100 units/ml should reduce their dose by 20%.

Refer to Toujeo® Summary of Product Characteristics for extended prescribing recommendations.

Give a Patient Guide to your patient and recommend he/she reads it carefully, as well as the Instructions for Use leaflet provided in the Toujeo® packaging.

Invite your patients to take the guide when he/she goes to the pharmacy.

Reporting of suspected adverse reactions or medication errors:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions or medication errors via HPRA Pharmacovigilance.

Website: www.hpra.ie

Adverse events or medication errors should also be reported to Sanofi by telephone on 01 403 5600 or via e-mail IEPharmacovigilance@sanofi.com