

# 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

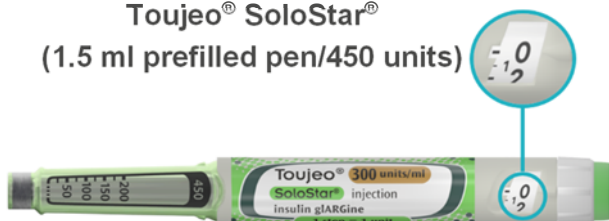
- This document is supplied as a guide to avoid medication errors. Please refer to the Summary of Product Characteristics before prescribing and dispensing a Toujeo® pen.
- Please provide your patients with the Patient Guide prior to prescribing or dispensing Toujeo® for the first time or when switching 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®

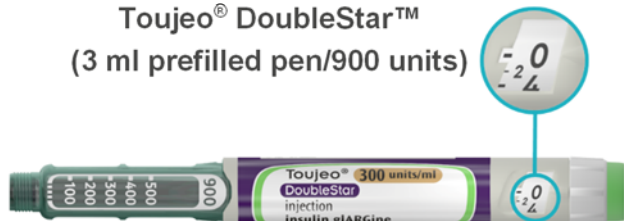
- ✓ Trade name and concentration (Toujeo® SoloStar® 300units/ml [or Toujeo® DoubleStar™ 300units/ml])
- ✓ Recommended daily dose in units according to the different situations outlined

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

Toujeo® SoloStar®  
(1.5 ml prefilled pen/450 units)



Toujeo® DoubleStar™  
(3 ml prefilled 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.


Toujeo® (Insulin glargine 300 units/ml) is available in different packaging and pack sizes depending on location within the United Kingdom.

Great Britain

**Toujeo®** 300 units/ml  
**SoloStar®**  
 solution for injection in a pre-filled pen  
**insulin glARGine**  
 Use only in this pen or severe overdose can result.  
 Subcutaneous use  
 3 pens

1 step = 1 unit  
 450 units per pen

sanofi



**Toujeo®** 300 units/ml  
**DoubleStar**  
 solution for injection in a pre-filled pen  
**insulin glARGine**  
 Use only in this pen or severe overdose can result.  
 Subcutaneous use  
 3 pens

1 step = 2 units  
 900 units per pen

sanofi




Northern Ireland

**Toujeo®** 300 units/ml  
**SoloStar®**  
 solution for injection in a pre-filled pen  
**insulin glARGine**  
 Use only in this pen or severe overdose can result.  
 Subcutaneous use  
 5 pens

1 step = 1 unit  
 450 units per pen

sanofi



**Toujeo®** 300 units/ml  
**DoubleStar**  
 solution for injection in a pre-filled pen  
 oplossing voor injectie in een voorgevulde pen  
**insulin glARGine / insuline glARGine**  
 Use only in this pen or severe overdose can result.  
 Alleen in deze pen gebruiken, anders kan ernstige overdosering optreden.  
 Subcutaneous use / Subcutaan gebruik  
 3 pens / pennen

1 step = 2 units  
 1 stap = 2 eenheden  
 900 units per pen  
 900 eenheden per pen

sanofi



## 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®

#### Switch from insulin glargine 100 units/ml to Toujeo®

- 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® 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®

- 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®** can be done unit-to-unit based on previous dose.
- **Switching from twice-daily basal insulins to once-daily Toujeo®**, the recommended initial Toujeo® 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® to other basal insulins

- Switching from Toujeo® (insulin glargine 300 units/ml) to Lantus® (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® to a once daily regimen with Lantus® 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.**

**Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:**

- The Yellow Card website, [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)
- The free Yellow Card app available from the Apple App Store or Google Play Store
- Some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours. When reporting please provide as much information as possible. By reporting, you can help provide more information on the safety of this medicine. Adverse drug reactions should also be reported to Sanofi: Tel: 0800 0902314. email: [uk-drugsafety@sanofi.com](mailto:uk-drugsafety@sanofi.com)