Toujeo® SoloStar prefilled pen (insulin glargine 300 units/ml)

Guide for healthcare professionals

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

This educational guide has been requested by the Committee for Medicinal Products for Human Use as additional risk minimisation for Toujeo. Healthcare professionals must also refer to the Prescribing Information for Toujeo® before prescribing and dispensing this pen, and advise patients to read the full instructions for use leaflet accompanying the pen.

Important information on dosing when prescribing Toujeo®

Toujeo SoloStar® is a prefilled pen that contains insulin glargine 300 units/ml. Toujeo has been approved for treatment of diabetes mellitus in adults. Toujeo® (insulin glargine 300 units/ml) and insulin glargine 100 units/ml are **not bioequivalent and are therefore not interchangeable without dose adjustment.**

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

✓ Trade name and concentration (Toujeo® SoloStar® 300 units/ml)

✓ Recommended daily dose in units according to the different situations outlined

The dose window of the Toujeo® SoloStar® pen shows the number of units of Toujeo® to be injected.

Initiation

✓ Patients with type 1 diabetes mellitus: Toujeo® is to be used once daily in combination with meal time insulin and the dose adjusted according to individual response

✓ Patients with type 2 diabetes mellitus: the recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments

Switch from insulin glargine 100 units/ml to Toujeo®

✓ Switching from insulin glargine 100 units/ml to once-daily Toujeo® can be done unit-to-unit based on previous dose.

A higher Toujeo dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels.

Switch from other basal insulins to Toujeo®

✓ 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.

When switching from a treatment regimen with an intermediate or long-acting insulin product to a regimen with Toujeo®, a change of the dose of the basal insulin may be required and the concomitant anti-hyperglycaemic treatment may need to be adjusted.

Switch from Toujeo® to insulin glargine 100 units/ml or other basal insulin products

✓ Patients who are changing their basal insulin regimen from 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%.
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 – the dose of insulin glargine 100 units/ml should therefore be reduced.

Close metabolic monitoring is required during any switch and in the initial weeks thereafter.

Advice to patients

✓ Explain to your patient that Toujeo® is not bioequivalent and not interchangeable with any other basal insulin including insulin glargine 100 units/ml, without individualized dose adjustment. Blood glucose monitoring by patients is needed during the switch and the initial weeks thereafter.

✓ Give a patient card to your patient and recommend they read it carefully, as well as the instructions for use leaflet provided in the Toujeo® Solostar® packaging. Invite your patient to take the card when he/she goes to the pharmacy.

Refer to Toujeo® Summary of Product Characteristics for extended prescribing recommendations.
Reporting adverse events: Please report medication errors or any side effects suspected to be associated with the use of Toujeo SoloStar pen. Reporting forms and information can be found at yellowcard.mhra.gov.uk. Adverse events should also be reported to Sanofi, by telephone on 01483 554 242 or email uk-drugsafety@sanofi.com.