Toujeo® (insulin glargine 300 units/ml)
Guide for healthcare professionals
Key safety elements when switching from or to an insulin with a different strength

This is supplied as a guide only. Healthcare professionals must 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® (insulin glargine 300 units/ml) and Lantus® (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 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.

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.

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Adjustments during the initial weeks

Dose adjustment may be needed when patients are switched to an insulin with a different strength.

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

- ✓ The Toujeo® dose regimen (dose and timing) should be adjusted according to individual response to treatment. In clinical trial setting, after initial titration, on average, a 10-18% higher basal insulin dose was needed to achieve target ranges for plasma glucose levels when using the 300 units/ml formulation compared to the insulin glargine 100 units/ml formulation

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

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

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 once daily Toujeo® (insulin glargine 300 units/ml) to a once daily regimen with Lantus® (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 card to your patient and recommend he/she must 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.

Call for reporting: Healthcare professionals should report any adverse events suspected to be associated with the use of Toujeo® SoloStar® to Sanofi Malta Ltd., 3rd Floor, Avantech Building, St. Julian's Road, San Gwann SGN 2805. Tel: 21493022, fax 21493024

Alternatively any suspected ADRs and medication errors can be reported to the Medicines Authority. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 MALTA, or sent by email postlicensing.medicinesauthority@gov.mt