Toujeo® (insulin glargine 300 units/mL) Guide for healthcare professionals

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

This is supplied as a guide only. Healthcare professionals must refer to the Product Information for Toujeo before prescribing and dispensing the Toujeo SoloStar® 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 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 scenarios outlined below

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 with meal-time insulin and requires subsequent individual dose adjustments
- ✔ 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 on a unit-to-unit basis. A higher Toujeo® dose (approximately 10–18%) may be needed to achieve an individual's target plasma glucose range

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 the previous basal insulin 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 an intermediate or long-acting insulin schedule to one that includes Toujeo®, a change in the dose of short-acting or fast-acting insulin analogue product may be required and the concomitant antihyperglycaemic treatment may need to be adjusted.

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 the same as other basal insulins (including insulin glargine 100 units/mL) and that they must not switch between them without consulting a healthcare professional to adjust the dose. 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 dose was needed to achieve target ranges for plasma glucose levels when using Toujeo® compared to the 100 units/mL formulation.

Close blood glucose 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

When switching from Toujeo to insulin glargine 100 units/mL, the dose should be reduced (approximately by 20%) to reduce the risk of hypoglycaemia. Close blood glucose monitoring is recommended during the switch and in the initial weeks thereafter.

Refer to Toujeo® Product Information for full prescribing recommendations.

Give a patient guide 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.

Reporting adverse events: Please report medication errors or any side effects suspected to be associated with the use of Toujeo® SoloStar® pen to Sanofi, by telephone on 1800 818 806 or email medinfo.australia@sanofi.com

QR code link to instructional video

PBS information: This product is not listed on the PBS.

Please review Product Information before prescribing Toujeo.
Full Product Information is available from sanofi-aventis australia pty ltd at http://products.sanofi.com.au/aus_pi_toujeo.pdf or by calling 1800 818 806.

Minimum Product Information Toujeo (insulin glargine) **Indications:** Treatment of diabetes mellitus in adults. **Contraindications:** Hypersensitivity to insulin glargine or any of the excipients. **Precautions:** Not recommended for treatment of diabetic ketoacidosis; hypoglycaemia; switching between insulin glargine 100 U/mL and Toujeo; switching between other insulins and Toujeo; intercurrent illness; insulin antibodies; insulin label must always be checked before each injection to avoid medication errors between Toujeo and other insulins; pregnancy category B3; lactation; careful glucose monitoring and dose adjustments may be necessary in elderly patients; not studied in children; renal and hepatic impairment. **Interactions:** Oral antidiabetic medicinal products; cardiovascular, analgaesic, anti-inflammatory, neurological, antipsychotic agents (see full PI); antibiotics; corticosteroids, other hormonal therapies (see full PI); diuretics; protease inhibitors; sympathomimetic agents; lithium; alcohol; sympatholytics including ß-blockers; others, see full PI. **Adverse Effects:** Hypoglycaemia; visual impairment; injection site reactions; others, see full PI. **Dosage and Administration:** Subcutaneous, once daily. Not for intravenous use. Dose adjustment may be required e.g. if patient's weight or life-style changes or change in timing of insulin dose. The desired blood glucose levels as well as doses and timing of anti-diabetic medication must be determined and adjusted individually. Instruct patients to never re-use a needle. Toujeo must not be drawn from the cartridge of the pre-filled pen into a syringe. Insulin glargine 100 U/mL and Toujeo are not bioequivalent and are not directly interchangeable. Toujeo must not be diluted or mixed with any other insulin products. When switching from insulin glargine 100 U/mL or other basal insulin products to Toujeo, dose may need to be adjusted. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. ≥18 years. Date reviewed: 1 July 2015 Reference Document: PI, 30 June 2015.

Reference: 1. Toujeo Approved Product Information.

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Toujeo®
insulin glargine 300U/mL

SANOFI DIABETES