

This material was developed by Sanofi, as part of the risk minimization plan for TOUJEO™.
It is not intended for promotional use.

IMPORTANT DOSING INFORMATION

TOUJEO™ SoloSTAR® (insulin glargine 300 units/mL, solution for injection)
Key safety elements when switching from or to an insulin with a different strength

Please take careful note of important dosing information to ensure the safe and appropriate use of TOUJEO (insulin glargine 300 units/mL) for the treatment of diabetes mellitus in adults. Healthcare professionals must refer to the TOUJEO SoloSTAR Product Monograph before prescribing and dispensing the 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 a long-acting formulation of insulin glargine (300 units/mL). The pen contains a total of 450 units of insulin glargine.



Please do not forget to write on each prescription for TOUJEO

- ✓ Name and concentration (e.g. TOUJEO 300 units/mL)
- ✓ Recommended daily dose in units

Recommended Dose and Dosage Adjustment of TOUJEO

Starting dose in insulin-naïve patients

Patient with Type 1 diabetes mellitus

- ✓ The recommended starting dose of TOUJEO is approximately one-third to one-half of the total daily insulin dose. The remainder of the total daily insulin dose should be given as a short-acting insulin and divided between each daily meal. As a general rule, 0.2 to 0.4 units of insulin per kilogram of body weight can be used to calculate the initial total daily insulin dose in insulin naïve patients with type 1 diabetes.

Patient with Type 2 diabetes mellitus

- ✓ The recommended starting dose of TOUJEO is 0.2 units/kg of body weight once daily.

Starting Dose in Patients with either Type 1 or Type 2 Diabetes Already on Insulin Therapy

Switch from LANTUS 100 U/mL to TOUJEO

- ✓ **Insulin glargine 100 units/mL and TOUJEO are not bioequivalent and are not directly interchangeable.**

When switching from LANTUS® (insulin glargine 100 units/mL) to TOUJEO, the starting dose of TOUJEO can be the same as the LANTUS, but a higher daily TOUJEO dose may be needed to achieve target ranges for plasma glucose level.

Switch from other basal insulins to TOUJEO

- ✓ Switching from once-daily basal insulins to once-daily TOUJEO, the starting dose of TOUJEO can be the same as the previous once-daily 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.

Switch from TOUJEO to other basal insulins

- ✓ Please refer to the prescribing information of the medicinal product to which the patient is switching.

Medical supervision with close metabolic monitoring is recommended during the switch and in the initial weeks thereafter.

Adjustments during the initial weeks

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

- ✓ Changes in insulin strength may affect glycemic control and predispose to hypoglycemia or hyperglycemia and may result in the need for a change in dosage. These changes should be made cautiously and only under close medical supervision, and the frequency of blood glucose monitoring should be increased. For patients with Type 2 diabetes, dosage adjustments of concomitant oral anti-diabetic products may be needed.
- ✓ **Explain to your patient although TOUJEO contains the same active substance as insulin glargine 100 units/mL (LANTUS), these drugs are not the same product hence not interchangeable.**

- ⓘ An increase of blood glucose monitoring is recommended during the switch and in the initial weeks thereafter.

Important additional information related to TOUJEO SoloSTAR pre-filled pen

- The dose pointer of the TOUJEO SoloSTAR pen shows the number of TOUJEO units to be injected.
- The TOUJEO SoloSTAR pre-filled pen has been specifically designed for TOUJEO, therefore **no dose re-calculation is required.**
- **TOUJEO must never be drawn from the cartridge of the pre-filled pen into a syringe**
- Patients must also be instructed **to not re-use needles.**
- Opened pre-filled pen must be discarded after 42 days (6 weeks) from the first use.

Refer to the full Product Monograph (PM) for extended prescribing recommendations. The TOUJEO SoloSTAR PM can be found at www.sanofi.ca or by contacting the sponsor. For additional medical information, please call Sanofi at [1-888-852-6887](tel:1-888-852-6887). This information is also posted on the Sanofi website.

The key safety elements are also available in the TOUJEO Titration tool. This tool will be distributed by your sales representative. In the event you didn't receive this tool or require further copy of this material, please contact the Sanofi Customer Services department at [1-800-265-7927](tel:1-800-265-7927).

Please report any medication errors or adverse events suspected to be associated with the use of TOUJEO SoloSTAR to Sanofi, by telephone at [1-888-852-6887](tel:1-888-852-6887) or by email at canada.pharmacovigilance@sanofi.com.