# TOUJEO® SoloSTAR® AND TOUJEO® DoubleSTAR®

## (INSULIN GLARGINE 300 U/mL, SOLUTION FOR INJECTION)

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

## GUIDE FOR HEALTHCARE PROFESSIONALS

- This document is supplied to provide important information on the appropriate use of TOUJEO® in patients with diabetes and to help minimize the risk of medication errors. Please refer to the Product Monograph for complete information.
- Please provide your patients with the Patient Tear Sheet when prescribing or dispensing TOUJEO® to ensure your patients and their caregivers are adequately informed on how to use TOUJEO® to help reduce the risk of medication errors. Advise patients to also read the Instructions for Use leaflet provided in their product packaging.

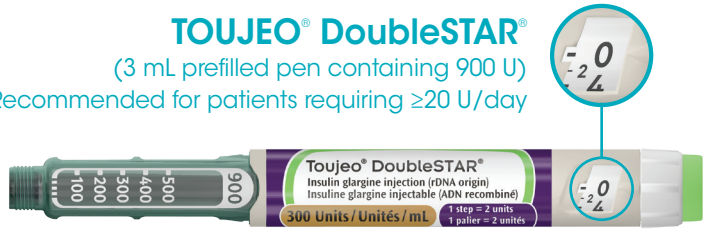
### Important information on adjustments during the initial weeks when prescribing TOUJEO®

- **LANTUS® (insulin glargine 100 U/mL) and TOUJEO® (insulin glargine 300 U/mL) are not bioequivalent and are not directly interchangeable** without dose adjustment
- Dose adjustment may be needed when patients are switched between different insulins
- Increased blood glucose monitoring is recommended during the switch and in the initial weeks thereafter

### TOUJEO® is available in two different presentations

**TOUJEO® SoloSTAR®**
(1.5 mL prefilled pen containing 450 U)


**TOUJEO® DoubleSTAR®**
(3 mL prefilled pen containing 900 U)
Recommended for patients requiring ≥20 U/day




**Remember to write on each prescription for TOUJEO®:**

- Name and concentration (e.g., TOUJEO® 300 U/mL)
- Device (e.g., SoloSTAR® or DoubleSTAR®)
- Recommended daily dose in units

**The dose increment is 1 U in TOUJEO® SoloSTAR® and 2 U in TOUJEO® DoubleSTAR®.**

The dose delivered is the one shown in the dose window.

TOUJEO® is indicated for once-daily subcutaneous administration in the treatment of adult and pediatric patients (6 years of age and older), with diabetes mellitus who require basal (long-acting) insulin for glycemic control.

Please consult the Product Monograph at http://products.sanofi.ca/en/toujeo-solostar.pdf for contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling 1.888.852.6887.

### Important information related to the TOUJEO® SoloSTAR® and TOUJEO® DoubleSTAR® prefilled pens

- The dose pointer shows the number of TOUJEO® units to be injected
- The TOUJEO® SoloSTAR® and TOUJEO® DoubleSTAR® prefilled pens have been specifically designed for TOUJEO®, therefore **no dose re-calculation is required**
- **TOUJEO® must never be drawn from the cartridge of the prefilled pen into a syringe**
- **Patients must also be instructed to not re-use needles**

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# RECOMMENDED DOSE AND DOSAGE ADJUSTMENT FOR TOUJEO®

## Starting dose in insulin-naïve patients

| | | |
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| **START** | Type 1 diabetes: | **0.2–0.4 U/kg**<br>**Approximately one-third to one-half of the total daily insulin dose.**<br>The remainder of the total daily insulin dose should be given as a short-acting insulin and divided between each daily meal. |
| | Type 2 diabetes: | **0.2 U/kg OD** |

## Starting dose in patients with Type 1 or Type 2 diabetes already on insulin therapy

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

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| **TRANSFER TO TOUJEO®** | Patients on OD basal insulin: | **1:1 conversion*** |
| | Patients on BID basal insulin: | **Start TOUJEO® at 80% of previous total daily basal insulin dose** |

**Monitor glucose frequently** in the first weeks of therapy and **titrate the dose of TOUJEO®** per instructions and the dose of other glucose lowering therapies per standard of care to minimize the risk of hyperglycemia when transferring patients to TOUJEO®.

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| **TRANSFER FROM TOUJEO®** | • Medical supervision with close metabolic monitoring is recommended during the switch and in the initial weeks thereafter |
| | • Please refer to the Product Monograph of the medicinal product to which the patient is switching |

Adapted from TOUJEO® SoloSTAR® and TOUJEO® DoubleSTAR® Product Monograph.
Please refer to the Product Monograph for complete dosing and administration instructions.

The TOUJEO® SoloSTAR® Product Monograph outlines that the full glucose lowering effect of TOUJEO® may not be apparent for at least 5 days.†

## REPORTING ADVERSE EVENTS

Please report medication errors or any suspected adverse events associated with the use of TOUJEO® to Health Canada or Sanofi.

**Health Canada**

1.866.234.2345

Visit the Adverse Reaction Reporting page for information on how to report online, by mail or by fax:
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

**Sanofi**

1.888.852.6887

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OD=once daily; BID=twice daily; SMBG=self-monitoring blood glucose; FBG=fasting blood glucose.
* LANTUS® and TOUJEO® are not bioequivalent and are not directly interchangeable. A higher daily TOUJEO® dose may be needed to achieve target ranges for plasma glucose level when switching from LANTUS®.
† Clinical significance has not been established.

**Reference:** TOUJEO® SoloSTAR® and TOUJEO® DoubleSTAR® Product Monograph, sanofi-aventis Canada Inc., May 12, 2020.

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