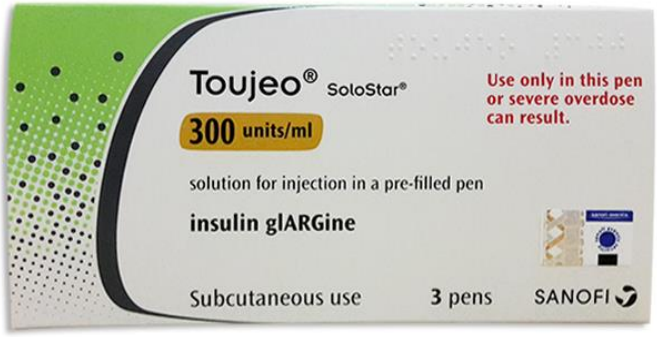
Insulin Toujeo® SoloStar® DoubleStar®
Product Information Sheet & Good Practice Guide



Insulin Toujeo® -Key Points

High strength basal Insulin product
Not bioequivalent to glargine or other insulins
Units are exclusive to the potency of Toujeo®
Dose adjustment is needed **if switching** patients to or from Toujeo®

This information sheet has been produced to summarise key information about insulin Toujeo for those providing care for a patient on this insulin, including on-going prescribing, supply or administration.

It is not specifically intended for diabetes specialists who are responsible for initiation and switching to/from insulin Toujeo®. Specialists are advised to refer to the SPC and local protocols for further information.

1. Insulin Toujeo® Product Information (Requires **SPECIALIST INITIATION** i.e. **Amber0)**

- Insulin Toujeo® contains **Insulin glargine 300 units/ml** in a pre-filled pen
- It is a **HIGH-STRENGTH Insulin Glargine product**
- It is a **basal insulin for ONCE DAILY use** (via subcutaneous injection)
- The potency of Toujeo® is stated in units**. These UNITS are EXCLUSIVE to Toujeo®** and are not the same as international units (IU) or the units used to express the potency of other insulin analogues
- Toujeo® is **NOT BIOEQUIVALENT** to Lantus or other basal insulins and **DOSE ADJUSTMENT** is needed when people are **SWITCHED to and from Toujeo®**
- Patients should only be switched to or from Toujeo® or initiated on treatment by a specialist in the care of diabetes. **Specialists are advised to refer to the SPC and local protocols for further information around initiation or switching.**
- It is metabolised in the same way as other insulin glargine products, but because of DIFFERENCES in FORMULATION it has a 'Flatter' and more prolonged insulin concentration (and glucose lowering activity) compared to alternative glargine products

- Toujeo® is supplied in a **pre-filled pen** and it should only be used with this device. The dose **counter of the pen** device **displays the number of units** of insulin.
- **NEVER** use a syringe to **withdraw insulin from a pre-filled pen** otherwise a severe overdose may result.
- **ALWAYS PRESCRIBE BY BRAND NAME and INCLUDE the CONCENTRATION of INSULIN** i.e. (Toujeo® SoloStar® 300 units/ml or Toujeo® DoubleStar® 300 units/ml)

2. Preventing Medication Errors

All staff should follow local organisational protocols regarding safe prescribing, storage and administration of Insulin. When insulin is prescribed, dispensed or administered, healthcare professionals should cross-reference available information to confirm the correct insulin products is used. The following recommendations are also suggested as a means of reducing the risk of errors with INSULIN TOUJEO®

2.1 PRESCRIBING (See also the SPC)

- Do not initiate or switch patients to or from insulin Toujeo® in non-specialist settings (Specialists are advised to refer to the SPC and local protocols for further information around initiation or switching).
- Toujeo® contains insulin glargine 300units/ml i.e. it is a high strength basal insulin and should be prescribed **ONCE DAILY**
- Prescribe by **BRAND** name and **INCLUDE THE CONCENTRATION** of insulin, (Toujeo® SoloStar® 300 units/ml or Toujeo® DoubleStar® 300 units/ml)
- Always **write the word 'UNITS' in full,** do not use abbreviations such as IU or U
- Patients should be given a patient information booklet and an Insulin Passport to help provide accurate identification of their current insulin products and provide essential information across healthcare sectors.

2.2 STORAGE

- **Before 1st use** store in a refrigerator (2°C-8°C). Do not freeze or place next to the freezer compartment or a freezer pack.
- There are over 20 different types of insulin. If involved in the supply of insulin, consider storing Insulin Toujeo® in a separate area of the fridge to minimise the risk of selection errors.
- Keep the pre-filled pen in the outer carton in order to protect from light

- **After 1st use** Insulin Toujeo® may be stored for a maximum of 6 weeks below 30°C and away from direct heat or direct light. **Pens in use should not be stored in the**

refrigerator. The pen cap should be put back on the pen after each injection in order to protect from light.

- Insulin Toujeo® should be stored in the patient's individual medicine locker, where these are available.

2.3 SUPPLY

- All **supplies should be labelled for individual patient use** and stock supplies to ward areas or clinics should be avoided. Labelling individual pens with patient details may further reduce the risk of the incorrect insulin being used.
- All dispensing of insulin Toujeo® should be second checked.
- In the community or outpatient setting, patients should be asked to confirm the correct insulin has been supplied before the prescription is handed out or on delivery.
- In the inpatient setting consider adding additional safeguards to ensure that the insulin has be delivered to the correct location and is stored appropriately. E.g. ward staff to sign for receipt, or pharmacy staff deliver the product directly.

2.4 ADMINISTRATION

- Each Toujeo® SoloStar® prefilled pen contains 450 units in total and a dose of 1-80 units can be given in one injection. Follow the Instructions for Use included in the package leaflet.
- Each Toujeo® DoubleStar® prefilled pen contains 900 units in total and a dose of 2-160 units can be given in one injection (**doses are selected in steps of 2 units at a time**). Follow the Instructions for Use included in the package leaflet.
- The Insulin label should always be checked before each injection to avoid medication errors between Toujeo® and other insulins. The strength "300" is highlighted in honey gold on the lab.
- The dose window shows the number of Toujeo® units to be injected. The Toujeo® SoloStar® and DoubleStar® pre-filled pens have been specifically designed for Toujeo®, therefore no dose re-calculation is required.
- Toujeo® is administered subcutaneously by injection in the abdominal wall, the deltoid or the thigh. Before using, the pen should be stored at room temperature for at least 1 hour. Injection sites should be rotated within a given injection area from one injection to the next.
- Patients should be encouraged to draw up and self-administer their insulin safely and independently.
- Where patients are unable to self-administer, they should visually verify the number of selected units on the dose counter of the pen. Patients who are blind or have poor vision should be instructed to get help/assistance from another person who has good vision and is trained in using the insulin device.
- **NEVER use a syringe to withdraw insulin from a pre-filled pen otherwise a severe overdose may result.**

2.5 Other

- Patients should carry identification with regards to their insulin at all times especially if admitted to hospital or if seeking advice from other health care professionals outside of the diabetes team. They should be encouraged to keep an insulin passport and to know the details of the type of insulin they use, including the dose.

- All staff involved in the prescribing, supply or administration of insulin should confirm the product and dose with the patient where possible.
- Patients and carers should ensure that they do not run out of insulin and have a system for ordering further supplies which accommodates this.
- Insulin Toujeo may not routinely be in stocked in community pharmacies or hospitals. Patients should bring a supply to hospital and should notify their community pharmacy in advance of their prescription running out.
- On transfer of care, or 1st dispensing staff should ensure that they verify the dose and type of insulin ideally using at least 2 sources. For example, the Summary of Care Record and the patient.

3 Initiating or Switching Patients to and From Insulin Toujeo ®

Insulin Toujeo® requires **SPECIALIST INITIATION** i.e. **Amber 0** Colour Classification, as such patients should only be initiated or switched to Insulin Toujeo® by a specialist in the care of diabetes. In this instance, local prescribing protocols should be followed (where they exist), in conjunction with the **SPC**.

As per the SPC patients should only be switched by from Toujeo® to another insulin under direct medical supervision, therefore this switch should also only be undertaken by specialists in the care of diabetes, in accordance with local prescribing protocols where they exist.

Switch from insulin glargine 100 units/ml to Toujeo®

- **Insulin glargine 100 units/ml and Toujeo® (insulin glargine 300 units/ml) are not bioequivalent and are therefore not interchangeable** without dose adjustment.
- Dose adjustment may be needed when patients are switched to an insulin with a different strength.
- Toujeo® dose regimen (dose and timing) should be adjusted according to individual response to treatment. After titration, on average a 10–18% higher basal insulin dose is needed to achieve target ranges for plasma glucose levels when using Toujeo® 300 units/ml formulation compared to the 100 units/ml formulation.

Switch from other basal insulins to Toujeo®

- When switching from a treatment regimen with an intermediate or long-acting insulin product to a regimen with Toujeo® 300 units/ml, a change in the dose of the basal insulin may be required and the concomitant anti-hyperglycaemic treatment may need to be adjusted. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter.
- **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.
- Blood glucose monitoring by patients is needed during the switch and the initial weeks thereafter.

Switch from Toujeo® to other basal insulins

- 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 an insulin regimen with once daily Toujeo® to a once daily regimen with Lantus® should reduce their dose by 20%.

Version Control.

Please access via the LMMG website to ensure the correct version is in use.

Version	Date	Amendments Made	Author
1.0	9th June 2016		Susan McKernan
1.1	14th June 2019	Updated to include information about DoubleStar®	Paul Tyldesley
1.2	April 2024	Additional of switching information from risk materials section of SPC	PT/AGR

References

1. SPC. Insulin Toujeo. Accessed Via the Electronic Medicines Compendium. at: https://www.medicines.org.uk/emc/medicine/30586
2. UKMI. In use product safety assessment report for Toujeo® and Abasaglar® (Insulin Glargines). Accessed via: http://www.ukmi.nhs.uk/filestore/ukmiaps/InsulinglarginesOct-2015_1.pdf
3. Drug Safety Update. High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error. MHRA April 2015. Accessed via: https://www.gov.uk/drug-safety-update/high-strength-fixed-combination-and-biosimilar-insulin-products-minimising-the-risk-of-medication-error
4. Patient Safety Alert. Passport to Safer use of insulin. NRLS. 2011. Accessed via: http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=130397&q=0%C2%ACinsulin%C2%AC
5. Rapid Response Alert. Safer Administration of Insulin. NRLS.2010. Accessed via: file:///C:/Users/susan.mckernan/Downloads/NRLS-1243-Safer%20administr-nsulin-2010.06.16-v1.pdf
6. Toujeo® (insulin glargine 300 units/ml) Important safety information guide for healthcare professionals. Accessed via https://www.medicines.org.uk/emc/rmm/336/Document (April 2024)

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