NHS
Herts Valleys
Clinical Commissioning Group

NHS
East and North Hertfordshire
Clinical Commissioning Group

Insulin glargine 300 units/ml (Toujeo®) Prescribing Support Information

- **Toujeo® (insulin glargine 300 units/ml) is a high-strength, ultra-long acting basal insulin recommended for restricted use in adult patients (aged 18 years and over) with type 1 and type 2 diabetes (see below).**
- **For specialist initiation and only transferred to the GP when patients are stable (AMBER INITIATION).**
- **Prescribe by brand name only.**
- **Prescribing restricted to Toujeo® Solostar (1.5ml pens) to minimise risk of error with the Toujeo® Doublestar (3ml pens).**
- **Patients to be given the appropriate insulin safety card (passport).**

HMMC Decision July 2020

Toujeo® (insulin glargine 300 units/ml) is **RECOMMENDED FOR RESTRICTED USE** in certain adult patients (aged 18 years and over) with **TYPE 1 and TYPE 2 DIABETES FOLLOWING INITIATION BY A SPECIALIST** who fulfil the following criteria:

- Patient with significant nocturnal hypoglycaemia, despite optimal adjustments of lifestyle (eliminating any contributory factors), diet (undertaken structured education e.g. DAFNE, DESMOND) and optimisation of basal insulin/multiple daily injections.
- "Chaotic patient" who may be at significant risk of diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic state (HHS) (previously known as hyperosmolar non-ketotic diabetic state or hyper HONK) if daily basal insulin is missed, despite optimal adjustments of lifestyle, and diet and optimising basal insulin/multiple daily injections.
- Patients with psychological problems (e.g. eating disorders or patients with intermittent compliance issues with insulin injections), who are not supervised by a daily carer and do not qualify to receive district nurse injections of daily insulin glargine, and who may be at significant risk of DKA or HHS if daily basal insulin is missed.
- Patients with a diagnosed allergy to either insulin detemir or insulin degludec.

Initiation, titration and stabilisation must be undertaken by consultants or consultant led specialist team (for a minimum of 3 months or until stable). Once stabilised for continuation in primary care. Patients should be monitored and reviewed by the initiating specialist team within 6 months of initiation to assess response. Patients with significant nocturnal hypoglycaemia should demonstrate an objective evidence of improvement between pre- and 6-month post treatment and returned to previous treatment, by the specialist, if no improvement in overall disease control from baseline is demonstrated.

Licensed Indication

Toujeo® (insulin glargine 300 units/ml) is licensed for the treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years. **NB – HMMC considered/approved Toujeo® for adult patients (aged 18 years and over) only; use of Toujeo® for paediatric patients is therefore not approved within Hertfordshire.**

Dosage

Toujeo® is a basal insulin for once-daily administration at any time of the day, preferably at the same time every day. The dose regimen (dose and timing) should be adjusted according to individual response.
The SmPC states that in type 1 diabetes mellitus, Toujeo® must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements; in patients with type 2 diabetes mellitus, Toujeo® can also be given together with other anti-hyperglycaemic medicinal products.

Safety

The potency of Toujeo® is stated in units. These units are exclusive to Toujeo and are not the same as IU or the units used to express the potency of other insulin analogues. Toujeo® is not bioequivalent to insulin glargine 100 units/ml (Lantus®) and not directly interchangeable with other insulin glargine products, insulin degludec (Tresiba®) or other insulins.
Toujeo® is classified as a high strength insulin. High strength insulins have been associated with an increased risk of medication errors, due to the wrong product being supplied. HMMC have therefore published an implementation action plan to support safe implementation.

Patients should read and understand the patient leaflet and education material and should have training on the correct use of Toujeo®.

Ensure the patient has been given the appropriate insulin safety card (passport), that patients carry the card at all times and use it to check they have the correct insulin when receiving a prescription, when insulin is dispensed, or in situations when insulin is being given to them by another person.

Adverse effects

The European Product Assessment Report (EPAR) produced for the licensing process, states that the safety profile of Toujeo® is similar to that of insulin glargine 100 units/ml (Lantus®) and no additional safety signals were detected.
The most frequent adverse events are hypoglycaemia, lipohypertrophy and injection site reactions.

Monitoring

The most frequent adverse event is hypoglycaemia and clinicians should monitor for this as with other insulin therapy. Patients will be monitored in secondary care until stable. Any concerns regarding a patient's therapy should be directed to the relevant specialist diabetes team.

References

Scottish Medicines Consortium: Insulin glargine (Toujeo®):
https://www.scottishmedicines.org.uk/medicines-advice/insulin-glargine-toujeo-abbreviatedsubmission-107815/
MHRA Drug Safety Update April 2015 *High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error*:
https://www.gov.uk/drug-safety-update/high-strength-fixed-combination-and-biosimilar-insulin-products-minimising-the-risk-of-medication-error
UKMi safety assessment report for Toujeo and Abasaglar (October 2015):
https://www.ukmi.nhs.uk/filestore/ukmiaps/InsulinglarginesOct-2015_1.pdf
European Product Assessment Report for Toujeo® Sanofi Aventis. August 2015:
https://www.ema.europa.eu/

Version	1.0
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