Insulin degludec (Tresiba®) Prescribing Support Information

- **Insulin degludec is an ultra-long acting basal insulin analogue recommended for restricted use in patients 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 only**
- **Prescribing restricted to insulin degludec (Tresiba®) 100units/ml to minimise any risk of error with the higher 200units/ml strength**
- **Patients to be given the appropriate insulin safety card (passport)**

HMMC Decision December 2018

Insulin degludec (Tresiba®) is **RECOMMENDED FOR RESTRICTED USE** in certain patients 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) and diet (undertaken structured education e.g. DAFNE) and optimising basal insulin/multiple daily injections who fulfil the criteria for insulin pump therapy.
- "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 glargine or insulin detemir.

Initiation, titration and stabilisation must be undertaken by consultants or consultant led specialist team. 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

Insulin degludec (Tresiba®) is licensed for the treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year.

Dosage

Insulin degludec is given once daily by subcutaneous administration at any time of the day, preferably at the same time every day. On occasions when this is not possible, there can be some flexibility in the timing of insulin administration. The SPC states that a minimum of 8 hours between injections should always be ensured. Tresiba® is to be dosed in accordance with the individual patient's needs.

Safety

Tresiba® is not simply interchangeable with other long-acting insulins. Tresiba® 100 units/ml solution for injection is available in pre-filled pen (FlexTouch®) and cartridge (Penfill). The pre-filled pen and cartridge contain 300 units of insulin degludec in 3 ml solution. The dose-counter window of the pen device shows the number of units. One dose step on the 100units/ml pen is equivalent to one unit of Tresiba®.

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

Tresiba® is available in 100units/ml strength and an additional higher strength 200units/ml. According to a MHRA drug safety update (April 2015) high strength insulin may be associated with an increased risk of medication errors, due to the wrong product being supplied. Therefore **to minimize any risk of error with the higher strength, prescribing locally has been restricted to only Tresiba® 100 units/ml.**

Ensure the patient has been given the appropriate insulin safety cards (passports), 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 safety profile of Tresiba® is largely similar to that of insulin glargine. The most frequent adverse events are injection site reactions. The most frequent severe adverse event is hypoglycaemia.

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.

Refer to SPC for full prescribing information: http://www.medicines.org.uk/emc/

References

Scottish medicines Consortium: insulin degludec (Tresiba®)
http://www.scottishmedicines.org/SMC_Advice/Advice/856_13_insulin_degludec_Tresiba/insulin_degludec_Tresiba_2nd_Resubmission
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

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