

## Tresiba® (Insulin degludec) Prescribing Support

- Tresiba® insulin degludec 100 units/ml and the high strength insulin 200units/ml
- Insulin degludec is not recommended for routine use in adults or children in either Type 1 or Type 2 diabetics and may only be of benefit to certain patients (see below)
- Specialist initiation only transferred to the GP only when patients are stable
- Prescribe by brand only
- Patients be given the appropriate insulin safety card (passport)

### Licensed Indication

Tresiba® (Insulin degludec) is licensed for the treatment of diabetes mellitus in adults

### MOPB Decision June 2016

Restricted to those patients with uncontrolled HbA1c (>7.5%/ 58 mmol/mol) who require basal insulin and have:-

- high insulin dose with significant insulin resistance (>1unit insulin/kg) and/or
- experiencing recurrent episodes of severe nocturnal hypoglycaemia.
- Specialist initiation only, transferred to the GP only after 3 months when patients have proven benefit in HbA1c and stable with prescribing support. HbA1c measured by Specialist prior to transfer.
- Prescribe by brand only

Treatment should be **initiated only under hospital or specialist supervision.**

### Safety

Tresiba® is an ultra-long acting basal insulin for once-daily subcutaneous administration at any time of the day. Insulin degludec 200units/ml is a high strength insulin. It is not simply interchangeable with other long-acting insulins and there is a potential risk of medication error. The dose-counter window of the pen device shows the number of units. One dose step on the 100 units/mL pen is equivalent to one unit of Tresiba®. One dose step on the 200 units/mL pen is equivalent to 2 units of Tresiba®.

Patients should read and understand the patient leaflet and education material and should have training on the correct use of Tresiba®. See MHRA Drug Safety Update April 2015 *High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error* for more information <https://www.gov.uk/drug-safety-update/high-strength-fixed-combination-and-biosimilar-insulin-products-minimising-the-risk-of-medication-error#high-strength-insulin-products>

Ensure the patient has been given the appropriate insulin safety cards (passports), 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

### Dosage

Insulin degludec is given once daily 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.

### 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. Cardiovascular safety studies are being undertaken to determine whether there is an increased risk with Tresiba®

See BNF for full details or SPC <https://www.medicines.org.uk/emc/medicine/27360>

### 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 can be directed to the diabetes team at Princess Alexandra Hospital (Diabetes-Endo@nhs.net).

### References

**Tresiba® Summary of Product Characteristics (SPC). Sanofi** <https://www.medicines.org.uk/emc/medicine/27360>

NICE Evidence summary: new medicine ESNM24 Sept 2013 Type 1 diabetes: insulin degludec  
<https://www.nice.org.uk/advice/esnm24/chapter/key-points-from-the-evidence>

NICE Evidence summary: new medicine ESNM25 Sept 2013 Type 2 diabetes: insulin degludec  
<https://www.nice.org.uk/advice/esnm25/chapter/key-points-from-the-evidence>

Scottish medicines Consortium: insulin degludec (Tresiba®)

[http://www.scottishmedicines.org/SMC\\_Advice/Advice/856\\_13\\_insulin\\_degludec\\_Tresiba/insulin\\_degludec\\_Tresiba\\_2nd\\_Resub\\_mission](http://www.scottishmedicines.org/SMC_Advice/Advice/856_13_insulin_degludec_Tresiba/insulin_degludec_Tresiba_2nd_Resub_mission)