MHRA
Regulating Medicines and Medical Devices

Drug Safety Update
Volume 6, Issue 9 **April 2013**
Latest advice for medicines users

Insulin degludec (Tresiba▼): available in additional higher strength than existing insulins—care needed to minimise risk of error, including training for patients

Article date: 24 April 2013

Summary
Insulin degludec (Tresiba▼) is available in prefilled pen devices (known as FlexTouch) in two strengths: 100 units/mL; and 200 units/mL. The 100 units/mL strength is also available in cartridge form (called Penfill). The 200 units/mL strength is higher than that of other existing basal insulin products in the UK. Ensure the correct insulin product and strength is prescribed and dispensed.

The dose-counter window of the Tresiba FlexTouch pen device shows the number of units that will be injected, irrespective of strength. Therefore no dose conversion is needed when transferring a patient from one strength of Tresiba to a different strength.

Patients should be trained on the correct use of Tresiba products, and always visually verify the dialled units on the dose counter of the prefilled pen device (irrespective of strength). Advise patients to seek medical advice immediately if they think they have administered an incorrect dose of Tresiba

Insulin degludec (Tresiba▼) has been developed as a once-daily basal insulin for the treatment of glycaemia in adult patients with diabetes mellitus. While administration at the same time of day is preferable, Tresiba allows for some flexibility in the timing of insulin injections. A minimum of 8 hours between injections should always be ensured.

Tresiba is available in pre-filled pen devices (called FlexTouch) in two strengths: 100 units/mL; and 200 units/mL. The 100 units/mL strength is also available in cartridge form (called Penfill, for use in specific insulin delivery systems). The prefilled pen devices have a dose-counter window that shows the number of units of insulin degludec that will be injected, irrespective of strength. Therefore no dose conversion is needed when transferring a patient from one strength of Tresiba to a different strength.

Patients should be trained on the correct use of the Tresiba products, in particular how to check the dose displayed on the prefilled pen device. Ensure that the strength is included on the prescription and dispensing label. Patients should be aware of the different strengths.

The pens and packaging of Tresiba are different for the two strengths. A letter on the safe use of Tresiba, including pictures of the different products, was sent to healthcare professionals in January 2013.

Advice for healthcare professionals:

Prescribing:

- When prescribing insulin degludec, ensure that the strength is included on the prescription
- Do not convert (ie, recalculate) doses when transferring patients from one strength of insulin degludec to another—the pen device shows the number of units of insulin to be injected irrespective of strength

Dispensing:

- Pharmacists should ensure that the correct strength of insulin degludec is dispensed; if in doubt, contact the prescriber
- Pharmacists should ask patients to visually identify the strength of insulin degludec dispensed, and should ensure patients are able to read the dose counter of the pen device. Ask patients with poor vision to always seek assistance from a person who has good vision and is appropriately trained in use of the device

Administration:

- Patients and healthcare staff must never use a syringe to withdraw insulin from a prefilled pen or from a cartridge

Transfer from other medicines:

- Close glucose monitoring is recommended during the transfer and in the following weeks. Doses and timing of concurrent rapid-acting or short-acting insulin products or other concomitant antidiabetic treatment may need to be adjusted
- For most patients, changing the basal insulin to Tresiba can be done unit-to-unit based on the previous basal insulin dose with subsequent individual dose adjustments

Information to give to patients:

- Patients should be aware that there are two different strengths of insulin degludec, and should be informed that the pen device will calculate the dose of insulin that they need irrespective of strength, so they simply need check the dose-counter window of the pen device which displays the dose in units, and make sure this matches the dose they wish to administer. Patients must never count audible clicks to determine the dose of Tresiba to be administered
- Patients should be provided with a patient booklet and Insulin Passport (or safety card), and should be trained on the correct use of Tresiba before the product is prescribed or dispensed
- Warn patients that they should only use Tresiba as they have been trained because using it any other way may result in a dangerous overdose
- Patients must be instructed to always check the manufacturer's packaging and dispensing label before every injection to ensure they have the correct Insulin

Clinical management and storage:

- Healthcare providers should risk assess electronic and paper systems used to prescribe, dispense and administer Tresiba. Carefully check the product strength selected in electronic systems
- Risk assess the clinical storage arrangements for Tresiba to help ensure selection of the correct strength

Further information

BNF section 6.1: Drugs used in diabetes
NHS guidance on supporting safe treatment in diabetes
Article citation: Drug Safety Update April 2013, vol 6, issue 9: A1.