Tresiba® (insulin degludec)

A basal insulin with two strength options

Below is important safety information regarding insulin degludec (Tresiba®), a basal insulin for the treatment of diabetes mellitus in adults, adolescents and children from 1 year.[1] Tresiba® is introduced in two strengths — 100 units/mL and 200 units/mL — in the UK.

Summary

Tresiba® is indicated for for the treatment of diabetes mellitus in adults, adolescents and children from 1 year[1] and is available in two strengths — 100 units/mL and 200 units/mL.[1] The Tresiba® 200 units/mL strength is available in a pre-filled pen in order to provide a lower injection volume and the ability to dose up to 160 units per injection. The availability of a 200 units/mL insulin strength can be associated with the risk of medication errors which can potentially lead to over- or under dosing.

Tresiba® 200 units/mL is only available in a pre-filled pen and like other pre-filled insulin pens, the dose is set on the dose dial in units. **No dose conversion should be done** when transferring patients between the two strengths. Tresiba® prescriptions must include the strength. Patients must be instructed on the correct use of Tresiba®, including verifying the name and strength of the product when receiving it and prior to every injection. Importantly, patients who are unable to read the dose counter on the pen must always be assisted by a person with good vision and who is trained in the use of the Tresiba® pre-filled pen. The information in this communication has been agreed with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Further information on the safety concern

As with all other insulin products, it is important not to risk mixing up different insulin strengths.

The two Tresiba® strengths are delivered in two distinct pen devices:

- Tresiba® 100 units/mL FlexTouch® pen can deliver insulin in steps of 1 unit, with a maximum of 80 units per injection
- Tresiba® 200 units/mL FlexTouch® pen can deliver insulin in steps of 2 units, with a maximum of 160 units per injection

Tresiba® FlexTouch® 100 units/mL pen

Tresiba® FlexTouch® 200 units/mL pen

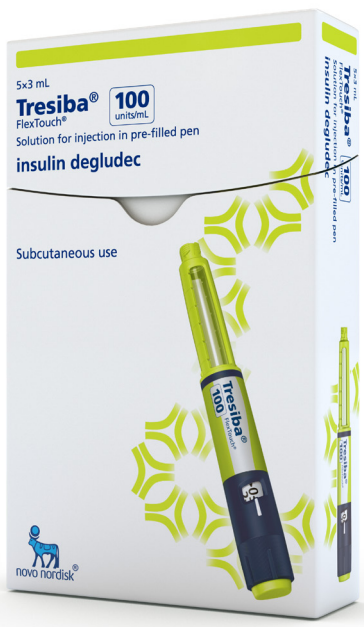
- The devices have a dose-counter window that shows the exact dose dialled. This means that the dose shown in the window is the dose that will be injected, regardless of strength. **Dose conversion should not be done** if transferring a patient to a new strength.

For patients who are colour blind, a tactile element has been added to the push-button to help differentiate the two formulations. This step is in addition to reading the formulation information on the packaging and pen.

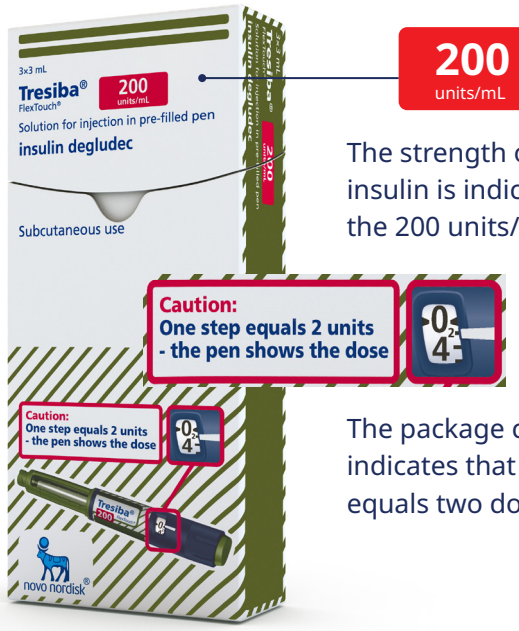
Further information on recommendations to healthcare professionals

- When prescribing, be sure to include the strength in the prescription. **Pharmacists must make sure to dispense the correct strength. If in doubt, contact the prescriber**
- As with all insulins, patients must always be appropriately trained in the correct use of the Tresiba® FlexTouch® pen
- Patients must visually verify the dialled units on the dose counter of the pen. Therefore, a requirement for patients to self-inject is that they can read the dose counter on the pen
- Patients must be instructed to always check the insulin label when they receive it at the pharmacy and before each injection to avoid accidental mix-ups between the two different strengths of Tresiba®
- As with all insulin products, patients who are blind or have poor vision must be instructed to always get help from another person who has good vision and is trained to use the insulin device
- The two strengths of Tresiba®, the packaging, and the respective pens have been designed to clearly differentiate between the two strengths. The Tresiba® 100 units/mL label and packaging are light green with a graphic design on the carton. The Tresiba® 200 units/mL label and packaging are dark green with striping. The Tresiba® 200 units/mL label and packaging also have a red box highlighting the strength. **Please see the illustrations on the right**
- Always follow the instructions for use of the FlexTouch® pen included in the product package. Never use a syringe to withdraw insulin from the pen

Tresiba® FlexTouch® 100 units/mL package 5 pens per carton



Tresiba® FlexTouch® 200 units/mL package 3 pens per carton



Dose conversion should not be done — the pen shows the dose in units.

Call for reporting

Adverse reactions to Tresiba®, including medication errors, should be reported to Novo Nordisk on 0800 023 2573 or local authorities. You can report via:
- The Yellow Card website — https://yellowcard.mhra.gov.uk/
- The free Yellow Card app available from the Apple App Store or Google Play Store
- Some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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Communication information

Education brochures for patients are available to healthcare providers in diabetes care, including pharmacies, in accordance with the local laws and practices, for distribution to all patients treated with Tresiba® 200 units/mL. If you have any questions, please contact our customer service centre at 0800 023 2573.

Reference: 1. Novo Nordisk Limited; GB Tresiba® SmPC.

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