Tresiba® (insulin degludec) Safety information poster

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Direct Healthcare Professional Communication on the association of insulin degludec (Tresiba®) with the risk of mixing up two strengths

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

Summary

Tresiba® is being introduced for the treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year and will be available in two strengths – 100 units/mL and 200 units/mL. The Tresiba® 200 units/mL strength is introduced 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 introduction 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 in the correct use of the 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 Health Products Regulatory Agency (HPRA).

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:

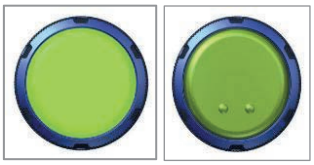
- Tresiba® 100 units/mL FlexTouch pen can deliver insulin in steps of 1 unit, with a maximum of 80 units per injection
- Tresiba® 200 units/mL FlexTouch pen can deliver insulin in steps of 2 units, with a maximum of 160 units per injection

Tresiba® FlexTouch® 100 units/mL pen

Up to 80 units per injection | 300 total units per pen | 1-unit dose adjustments

Tresiba® FlexTouch® 200 units/mL pen

Up to 160 units per injection | 600 total units per pen | 2-unit dose adjustments



Tresiba® 100 units/mL | **Tresiba® 200 units/mL**

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.

- The devices have a dose-counter window that shows the exact dose dialled. This means that the dose that is 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.

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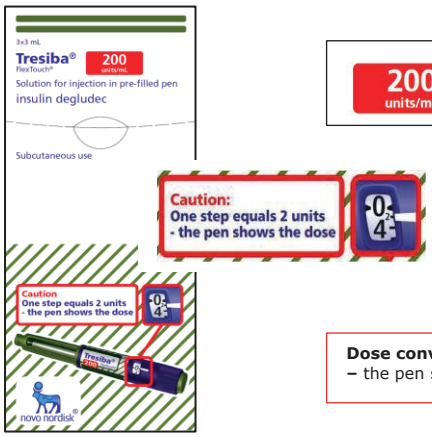
Further information on recommendations to healthcare professionals

- When prescribing make sure to include strength on the prescription. Pharmacists must make sure to dispense the correct strength, if in doubt contact the prescriber.
- As with all insulins, patients, their parents and/or care givers, 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, the 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/assistance from another person who has good vision and is trained to use the insulin device.
- The two strengths of Tresiba®, 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 illustrations below.

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

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



The strength of the insulin is indicated with a 200 units/mL label.

The package clearly indicates that one step equals 2 dose units.

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

- 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.

Call for adverse event reporting

Adverse reactions to Tresiba®, including medication errors, should be reported to Novo Nordisk on 01 862 9700. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Communication information

Education brochures for patients will be made 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.

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