January 2013

Direct Healthcare Professional Communication on the correct use of Tresiba® ▼ (insulin degludec) to minimise medication errors

Dear Healthcare Professional,

This letter is to inform you of important safety information regarding insulin degludec (Tresiba®), a new basal analogue insulin for the treatment of diabetes mellitus in adults.

Summary

- **Tresiba® is being introduced in two strengths – 100 units/mL and 200 units/mL – in the UK.**
- **The 200 units/mL strength is higher than that of other existing insulin products available in the UK.**
- **The information and recommendations below are provided in order to minimise the risk of medication errors when prescribing Tresiba®.**
- **Patients must be advised to seek medical advice immediately if they administer an incorrect dose of Tresiba®.**

The information in this communication has been agreed with the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Information on the correct use of Tresiba®

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.

The 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 while 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.

When switching between strengths of Tresiba® dose conversion should not be done – the pen shows the dose in units. ***Please see illustrations at the end of this letter (Further information on the correct use of Tresiba®).***

Recommendations to healthcare professionals

- The pre-filled pen devices that deliver Tresiba® have a dose-counter window that shows the exact dose dialled. The dose that is shown in the window is the number of units of Tresiba® that will be injected regardless of strength. **Dose conversion is not required if transferring a patient to a new strength of Tresiba®.**
- The prescriber should ensure that the strength of Tresiba® is included on the prescription.
- Pharmacists must ensure that the correct strength is dispensed, and, if in doubt, the pharmacist must contact the prescriber.
- Pharmacists must ask patients to visually identify the strength of Tresiba® they are dispensed.
- Patients prescribed Tresiba® should be provided with a patient brochure and must be trained on the correct use of the Tresiba® FlexTouch® pen before Tresiba® is prescribed or dispensed. Patients must never use a syringe to withdraw insulin from the pen or use the cartridge outside of the FlexTouch® pen.
- Patients who self-inject must be able to read the dose counter on the pen. Patients who are blind or have poor vision must be instructed to always get assistance from another person who has good vision and is trained to use the insulin device.
- Patients must be instructed to always check the manufacturer's packaging and dispensing label before each injection to ensure they have the correct strength of Tresiba®, to avoid accidental mix-ups.
- **Patients must be advised to seek medical advice immediately if they administer an incorrect dose of Tresiba®.**

For more information please refer to the Tresiba® Summary of Product Characteristics and Package Leaflet found at www.ema.europa.eu.

Call for reporting

Please report suspected adverse reactions and medication errors to the MHRA through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD".
- at the back of the British National Formulary (BNF).
- by telephoning the Commission of Human Medicines (CHM) free phone line: 0800 731 6789.
- or by electronic download through the Yellow Card section of the MHRA website (http://yellowcard.mhra.gov.uk/downloads/).

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Adverse events and medication errors should also be reported to the Novo Nordisk Customer Care Centre on 0845 600 5055 (calls may be monitored for training purposes).

Communication information

Education brochures for patients have been included with this correspondence, for distribution to all patients treated with Tresiba® FlexTouch®. An educational poster for display in diabetes clinics and pharmacies is also included with this letter.

If you have any questions, or if you require further copies of the patient education brochure, please contact our Customer Care Centre on 0845 600 5055.

Yours sincerely,

Dr. Anders Dyhr Toft,
Medical Director,
Novo Nordisk UK

Further information on the correct use of Tresiba®

Tresiba® FlexTouch® 100 units/mL pen

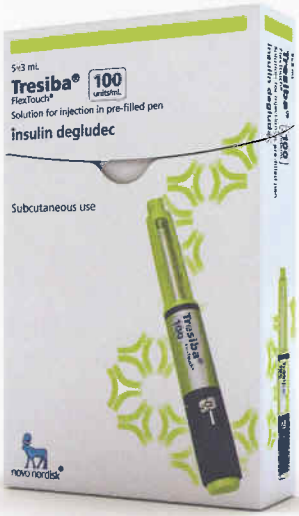
Tresiba® FlexTouch® 200 units/mL pen

Tresiba® 100 units/mL

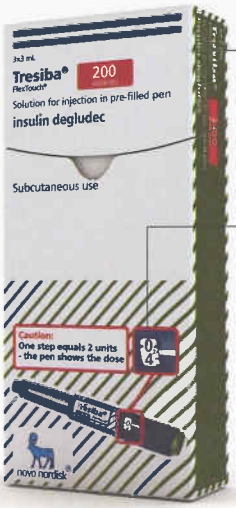
Tresiba® 200 units/mL

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.

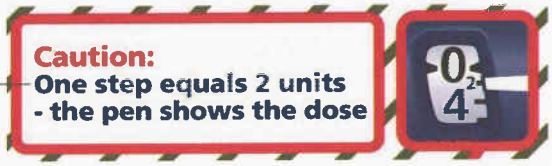
Tresiba® FlexTouch® 100 units/mL package 5 pens per carton



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.

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