UPDATED LETTER FOR MARCH 2024

March 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Tresiba® FlexTouch® 100 U/mL solution for injection (insulin degludec): Update for HCPs on Supply Shortage in the UK
and
Tresiba® FlexTouch® 200 U/mL solution for injection (insulin degludec): Information for HCPs on Dosing errors

Dear Healthcare Professional,

Novo Nordisk UK in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health and Social Care (DHSC) would like to inform you of the following:

- **An update on the supply shortage for Tresiba FlexTouch 100 U/mL solution for injection**
- **The potential for inappropriate dosing of insulin when switching Tresiba products**

Summary

- Tresiba FlexTouch is a once-daily insulin analogue indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.
- Novo Nordisk is currently experiencing a shortage of Tresiba FlexTouch 100 U/mL. The shortage is expected to continue until at least the end of 2024.
- It is important to ensure that patients currently using Tresiba FlexTouch 100 U/mL are supported to change to an alternative treatment as soon as possible. Please refer to the advice provided in the Medicines Shortage Notification (MSN) (MSN/2023/053- available on Medicine Supply Tool) and the National Patient Safety Alert (NatPSA) (NatPSA/2023/016/DHSC- available on MHRA Central Alerting System) issued by the DHSC.
- Ensure that patients who have been switched to Tresiba FlexTouch 200 U/mL are made aware that Tresiba FlexTouch pen delivery devices dial up in unit increments rather than volume and no dose change is necessary.
- Awareness of the digital health care professional (HCP) guide containing important safety information regarding insulin degludec (Tresiba), along with the patient brochure and the poster, emphasizing that no dose conversion should be done when transferring patients between the two strengths of Tresiba.

Background on the safety concern

Tresiba FlexTouch is a pre-filled pen designed to be used with NovoFine® or NovoTwist® injection needles. Please refer to the Summary of Product Characteristics (SmPC) for the detailed therapeutic indication (https://www.medicines.org.uk/emc/product/7936/smpc).

Novo Nordisk is experiencing a shortage of Tresiba FlexTouch 100 U/mL, which is expected to continue until at least the end of 2024. The shortage is not due to any safety or quality-related concerns. Other presentations of Tresiba, including within cartridges, and other strength of Tresiba FlexTouch are unaffected by the shortage. For more information on other presentations of Tresiba and compatible delivery system, please refer to Tresiba SmPC (www.medicines.org.uk/emc/search?q=tresiba) and Risk

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Minimisation Materials for device user guides (https://www.medicines.org.uk/emc/product/2944/rmms) available on emc.

A Medicines Shortage Notification (MSN/2023/053) was issued by the DHSC on 24/05/2023; this was then updated on 15/11/2023. This MSN is available on Medicine Supply Tool within the Specialist Pharmacy Service website. You may need to register to access the Medicine Supply Tool (www.sps.nhs.uk/wp-login.php).

A National Patient Safety Alert (NatPSA/2023/016/DHSC) was issued by DHSC on 08/12/2023 for immediate action by all organisations involved in prescribing, dispensing and administering Tresiba products. The NatPSA provides details on the potential for inappropriate dosing of insulin when switching Tresiba products and is available on MHRA Central Alerting System. (https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103242)

Advice for healthcare professionals:

You are urged to notify patients who are currently using the Tresiba FlexTouch 100 U/mL of the shortage and to support them to change to an alternative treatment as per advice provided in the MSN and NatPSA.

Delayed awareness of the out-of-stock situation, delayed action to support patients to change to an alternative treatment and incorrect prescribing, dispensing and administration of the required dose could result in patients missing the required doses, which may have clinical consequences, such as hyperglycaemia and eventually progression to diabetic ketoacidosis.

- The recommendation is to switch to an alternative insulin injection device other than Tresiba FlexTouch. Where this is not possible due to a patient's dexterity or ability to use the new device, seek advice from specialist diabetes teams on the use of an alternative insulin.

- If a switch to Tresiba Penfill 100 U/mL is deemed clinically appropriate, ensure the patient is also supplied with a compatible Novo Nordisk insulin delivery system and appropriate needles. Ensure all patients initiated on a new device are counselled on the change and are provided with training on use of the new device, including signposting to training videos, and the potential need for closer monitoring of blood glucose levels. Please refer to the device user guides available on emc to aid the transition.

- If a switch to Tresiba FlexTouch 200 U/mL may be necessary, clinicians **should not adjust the dose of insulin. Ensure that patients are made aware that Tresiba FlexTouch pen delivery devices dial up in unit increments rather than volume and no dose change is necessary.** For more details, please refer to the NatPSA and Risk Minimisation Material (including the HCP guide, patient brochure and poster) on risk of medication errors available on emc (https://www.medicines.org.uk/emc/product/7936/rmms).

- If a switch to an alternative long-acting basal insulin is deemed clinically appropriate, this should be done only after careful consultation with a physician and under strict medical supervision.

- No new patients should be initiated on Tresiba FlexTouch 100 U/mL and 200 U/mL during this shortage.

- Remind your colleagues of these actions, particularly if they are known to use/prescribe Tresiba FlexTouch.

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Please ensure that all relevant staff are made aware of the contents of this letter and that the information is communicated to the affected patients.

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions (ADRs) to the Yellow Card scheme.
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.

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

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point

If you have any questions about this letter or require more information about Tresiba FlexTouch 100 U/mL or alternative devices that support the use of Tresiba, please contact Novo Nordisk Customer Care Centre on 0800 023 2573.

Yours sincerely,

Dr. Avideh Nazeri
Vice President
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Avideh Nazeri

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