

Date: 16 June 2023



DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Tresiba® FlexTouch® 100 units/mL solution for injection (insulin degludec): Supply Shortage in the UK

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:

Novo Nordisk is experiencing a supply shortage for Tresiba® 100 units/mL solution for injection (insulin degludec), only within FlexTouch® pens in the UK.

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 experiencing a shortage of Tresiba U100 FlexTouch. We expect this to last from August 2023 until January 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/2023/053) issued by the DHSC.

Background on the safety concern:

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. 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 \(SmPC\)](https://www.medicines.org.uk/emc/product/7936/smpc) for the detailed therapeutic indication (<https://www.medicines.org.uk/emc/product/7936/smpc>).

Novo Nordisk is experiencing a shortage of Tresiba U100 FlexTouch, which is expected to last from August 2023 until January 2024. The shortage is not due to any safety or quality-related concerns for Tresiba FlexTouch 100 U/mL. Despite new investments in our manufacturing sites, high demand for our medicines has led to a shortage of our FlexTouch disposable injection pens, which are used to deliver many of our medicines and are one delivery option for Tresiba in a 100 U/ml dose. Other presentations of Tresiba, including within other insulin pens, are unaffected by the shortage.

A Medicines Shortage Notification (MSN) (MSN/2023/053) was issued by the DHSC on 24/05/2023. This is available on the Medicines Supply Tool within the Specialist Pharmacy Service website. You may need to [register](http://www.sps.nhs.uk/wp-login.php) to access the Medicines Supply Tool (www.sps.nhs.uk/wp-login.php).

Advice for healthcare professionals:

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

- You are urged to notify patients who are currently using the Tresiba FlexTouch 100U/ml of this issue and to support them to change to an alternative treatment as per advice provided in the MSN.
- As per DHSC advice, no new patients should be initiated on Tresiba FlexTouch 100 U/mL during this shortage.
- If a switch to an alternative insulin injection device for Tresiba 100 U/mL is deemed clinically appropriate, you may refer to the relevant device [user guides available on emc](#) to aid the transition (www.medicines.org.uk/emc/product/2944/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.
- Remind your colleagues of these actions, particularly if they are known to use/prescribe Tresiba FlexTouch 100 U/mL.

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 reactions 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, SystemOne, 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.

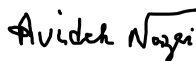
Company contact point

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.

I understand the uncertainty and concern this shortage may cause people living with diabetes. This is not something we are taking lightly, and we are working hard to solve these challenges.

Yours sincerely,

Dr. Avidah Nazari



Vice President

Clinical Development, Medical and Regulatory Affairs (CMR), Novo Nordisk UK