Date: March 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

DISCONTINUATION OF: NovoRapid® FlexTouch® 100 units/ml solution for injection in 3 ml pre-filled pen (insulin aspart) and Insulatard® Penfill® 100 units/ml suspension for injection in cartridge (isophane insulin human)

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:

Summary

- **Novo Nordisk has decided to discontinue NovoRapid® FlexTouch® 100 units/ml solution for injection 3ml pre-filled pen (insulin aspart) and Insulatard® Penfill® 100 units/ml suspension for injection in cartridge (isophane insulin human).**
- **This decision is not a consequence of any safety or quality related issues.**
- **The DHSC has issued Medicines Shortage Notifications for NovoRapid® FlexTouch® and Insulatard® Penfill® (MSN/2024/103 and MSN/2024/112 - available on the Medicine Supply Tool). Please refer to the advice provided.**
- **We expect to have supply of NovoRapid® FlexTouch® until the end of March 2025 and Insulatard® Penfill® until the end of June 2025.**
- **Do not initiate any new patients on NovoRapid® FlexTouch® and Insulatard® Penfill® ahead of the discontinuation date**
- **It is important to ensure that patients currently using NovoRapid® FlexTouch® and Insulatard® Penfill® are supported to change to an alternative treatment as soon as possible to avoid serious clinical consequences. Please refer to the advice provided by the Department of Health and Social Care on the Medicines Supply Tool hosted on the Specialist Pharmacy Service website (Medicine Supply Tool)**
- **Healthcare professionals must consider specific vulnerable patient populations, such as those with dexterity and visual impairment when switching to alternative products.**
- **Further consultation and guidance from specialist diabetes teams may be required on the use of an alternative insulin.**
- **Remind your colleagues of these actions, particularly if they are known to use/prescribe NovoRapid® FlexTouch® (insulin aspart) and Insulatard® Penfill® (isophane insulin human).**
- **Please ensure that all relevant staff, particularly those involved in handling repeat prescription requests, are made aware of the contents of this letter and that the information is communicated to the affected patients.**

Background on safety information

- NovoRapid® FlexTouch® and Insulatard® Penfill® are insulins indicated for the management of diabetes mellitus.
- This decision is not a consequence of any safety or quality related issues. To ensure stable product supply, we are consolidating our portfolio. As part of the portfolio consolidation, NovoRapid® FlexTouch® and Insulatard® Penfill®
  will be phased out. However, other presentations of these products will continue to be marketed. We acknowledge that this will be disruptive to people living with diabetes who rely on those treatments.

- The DHSC has issued Medicines Shortage Notifications (MSN/2024/103 and MSN/2024/112). These are 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). We kindly request you to use alternative products where needed. Refer to advice provided in the MSN. This should be considered along with the requirements in the Summary of Product Characteristics (SmPC).
- If patients are not timely switched to an appropriate alternative treatment option, this could result in patients missing the required doses, which may lead to serious clinical consequences, specifically hyperglycemia that may eventually progress to diabetic ketoacidosis.

Please refer to the SmPC for details of therapeutics indications:

NovoRapid FlexTouch: https://www.medicines.org.uk/emc/product/7921/smpc#
Insulatard Penfill: https://www.medicines.org.uk/emc/product/7886/smpc

Advice for healthcare professionals

- Healthcare professionals (HCPs) are urged to ensure that patients using NovoRapid® FlexTouch® and Insulatard® Penfill® are made aware of this discontinuation and safely switched to alternative insulins/insulin delivery systems at the HCPs' discretion and based on local routine clinical practices.
- Transitioning between different types of insulin/insulin delivery systems or to another brand or manufacturer of insulin should be done in consultation with the physician and requires strict medical supervision.
- HCPs are requested to provide clear instructions regarding the new insulin regimen and/or usage of the new insulin delivery system to the patient upon transition.
- HCPs are requested to follow product SmPCs/labels for dosing recommendations while switching patients to alternative products.
- The patients should be fully informed about the reason for the change in insulins/insulin delivery systems and the potential need for change in dose and additional glucose monitoring.
- Close glucose monitoring is recommended during the transfer to another type or brand of insulin and in the initial weeks thereafter.
- HCPs are requested to remind their colleagues of these actions, particularly if they are known to be prescribers of NovoRapid® FlexTouch® and Insulatard® Penfill®.

Call for reporting

HCPs are asked to report any suspected adverse drug reactions (ADRs) to the MHRA via the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- The Yellow Card website
- The free Yellow Card app available from the Apple App Store or Google Play Store
- Some clinical IT systems (EMIS, Sysmon, 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, please contact Novo Nordisk Customer Care Centre on 0800 023 2573.

Yours sincerely,

Avideh Nazeri 09.03.2025

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