

Date: October 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

DISCONTINUATION OF: Levemir® Penfill® and Levemir® FlexPen®

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 Levemir® Penfill® and Levemir® Flex-Pen®
- This decision is not a consequence of any safety or quality related issues.
- The DHSC has issued an updated Medicines Shortage Notifications for Levemir® Penfill® and Levemir FlexPen® on 14 August, along with joint clinical guidance provided by the Primary Care Diabetes & Obesity Society (PCDOS) and Association of British Clinical Diabetologists (ABCD) (MSN/2025/036U- available on the Medicine Supply Tool). Please refer to the advice provided.
- We expect to have supply of Levemir® Penfill® and Levemir FlexPen® until the end of December 2026.
- To aid patient awareness, in agreement with the MHRA, Novo Nordisk have updated the carton to include the wording: 'To be discontinued. Please speak to your healthcare professional for more information on timing and alternative medicine.' This will not be rolled out before next year.
- Do not initiate any new patients on Levemir® Penfill® and Levemir FlexPen®
- It is important to ensure that patients currently using Levemir® Penfill® and Levemir FlexPen® are supported to change to an alternative treatment in line with the joint clinical guidance. Please refer to the advice provided by the PCDOS and ABCD clinical guidance available on the PCDOS website.
- Avoid initiating widespread changes without checking the current supply overview of alternative insulins to reduce the risk of precipitating a supply disruption of these products. As recommended in the joint clinical guidance, clinicians should aim to diversify prescribing across available alternatives to reduce supply risk where possible
- 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 Levemir® Penfill® and Levemir® FlexPen®
- 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

- Levemir® Penfill® and Levemir FlexPen® 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, Levemir® Penfill® and Levemir FlexPen® will be phased out. 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/2025/036U). These are available on Medicine Supply Tool within the Specialist Pharmacy Service website. You may need to <u>register</u> to access the Medicine Supply Tool (<u>www.sps.nhs.uk/wplogin.php</u>). 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:

Levemir Penfill: https://www.medicines.org.uk/emc/product/7889/smpc Levemir Flexpen: https://www.medicines.org.uk/emc/product/7889/smpc

Advice for healthcare professionals

- Healthcare professionals (HCPs) are urged to ensure that patients using Levemir® Penfill® and Levemir FlexPen® 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 Levemir® Penfill® and Levemir FlexPen®.

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 <u>Apple App Store</u> or <u>Google Play Store</u>
- Some clinical IT systems 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,

Dr Avideh Nazeri

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Vice President

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