Date: April 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Levemir® InnoLet® 100 units/ml solution for injection in pre-filled pen (insulin detemir), Insulatard® InnoLet® 100 international units/ml suspension for injection in pre-filled pen (insulin isophane human), NovoTwist® 5mm needles (32G), NovoFine® 6mm needles (31G), NovoFine® 8mm needles (30G), NovoFine® Autocover® needle (30G) and NovoFine® Remover: DISCONTINUATION

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 InnoLet (an injectable device for insulin delivery), and also, the following needles: NovoTwist 5mm (32G) needle, NovoFine 6mm (31G) and 8mm (30G) needles, NovoFine Autocover needle (30G), and NovoFine Remover.**
- **The DHSC has issued Medicines Shortage Notifications for Levemir InnoLet and Insulatard InnoLet (MSN/2024/032 and MSN/2024/033). Please refer to the advice provided.**
- **Only the InnoLet presentation of Levemir and Insulatard is being discontinued.**
- **We expect to have supply of InnoLet until at least May 2024. Our range of affected needles will be available until December 2024 except our NovoTwist 5mm needle. The NovoTwist 5mm needle has already been out of stock for an extended period of time and will not return to stock.**
- **Please refer to the full advice within the MSNs issued by the DHSC.**
- **Do not initiate any new patients on InnoLet.**
- **It is important to ensure that patients currently on InnoLet are supported to change to an alternative as soon as possible. Please refer to the advice provided in the MSNs.**
- **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 to ensure that the patient is comfortable and fully trained on their new injectable device.**
- **Remind your colleagues of these actions, particularly if they are known to use/prescribe Insulatard InnoLet (insulin isophane human) or Levemir InnoLet (insulin detemir).**
- **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.**
- **A patient letter is available for patients using Levemir InnoLet (insulin detemir) and Insulatard InnoLet (isophane (NPH) insulin human). This can be provided to patients if required. This is also available on the emc website: https://www.medicines.org.uk/emc/product/7883 and https://www.medicines.org.uk/emc/product/7890.**

Background on safety information

- InnoLet was originally made available over twenty years ago. In that time, Novo Nordisk has seen a steady decline in demand for this medical device with the advent of newer and more innovative insulin delivery devices for people living with diabetes. We have also seen a steady decline in demand across our range of needles, with the advent of newer and smaller injection needles for patients in the UK and will continue to provide a 4mm NovoFine needle to eligible patients in the UK.
- InnoLet is a handheld insulin delivery device with a dial resembling an egg timer that Novo Nordisk developed nearly 20 years ago. The device is prefilled with 300 units and patients insert a needle and dial the dosage for the injection.
- Insulatard InnoLet is indicated for treatment of diabetes mellitus.
- Levemir InnoLet is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.
- We would like to highlight that this decision is not a consequence of any safety or quality related issues. It is based on several factors such as the availability of newer insulin delivery devices, scientific advancements in insulin delivery, changes in treatment practices, and steady reduction of the device around the world.
- The DHSC has issued Medicines Shortage Notifications (MSN/2024/032 and MSN/2024/033). This 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). **Please refer to the advice provided.** We kindly request you to use alternative products where needed. Refer to advice provided in the MSNs. This should be considered along with the requirements in the summary of product characteristics.
- Novo Nordisk remains committed to the ongoing development of new medicines and devices to help patients in managing their condition.

Please refer to the Summary of Product Characteristics (SmPC) for details of therapeutics indications
Insulatard InnoLet : https://www.medicines.org.uk/emc/product/7883
Levemir InnoLet : https://www.medicines.org.uk/emc/product/7890

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
- 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,

Dr Avideh Nazeri
Vice President
Clinical Development, Medical and Regulatory Affairs (CMR), Novo Nordisk UK