DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

NovoRapid® Penfill 100 units/ml solution for injection in cartridge (insulin aspart): supply of Stock with old Patient Information Leaflet to mitigate supply disruption in November 2022

Summary: Novo Nordisk A/S would like to inform you of measures taken to ensure continuity of supply of NovoRapid® Penfill 100 units/ml solution for injection in cartridge (insulin aspart) in Great Britain.

To ensure continuity in supply, Nordisk A/S has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply stock packaged with the old patient information leaflet, product batch LR77A19 (74640 packs) and batch LR77D24 (27120 packs) which is expected to be on Great Britain market for a period of seven weeks from **7th November to 31st December 2022**.

Please note the following:

- The product labelled with the batch numbers LR77A19 and LR77D24 has the same formulation as the Great Britain product.
- The aforementioned batches are manufactured according to the same manufacturing process and quality controls as the Great Britain product.
- There are minor differences between the aforementioned batches and GB product information. The PIL packaged with these batches omits safety information on the potential side effect of cutaneous amyloidosis and corresponding instructions to rotate injection site to help prevent changes to the fatty tissue under the skin' – see below for more information.
- As the medicinal products are identical to the approved GB product, these batches will be supplied as a temporary measure and can be dispensed to patients until we resume supply of GB stock with the currently approved PIL.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) for NovoRapid® are followed. For additional copies of the leaflet, please refer to NovoRapid® Penfill 100 units/ml - Patient Information Leaflet (PIL) - (emc) (medicines.org.uk) or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of **NovoRapid® Penfill 100 units/ml solution for injection in cartridge**.

Please ensure all relevant staff are made aware of the content of this email and that the information is communicated to the patients.

Missing information from the Patient Information Leaflet:

Details of the safety update that will not be present in the PIL supplied with the batches in November for the GB market are as follows:

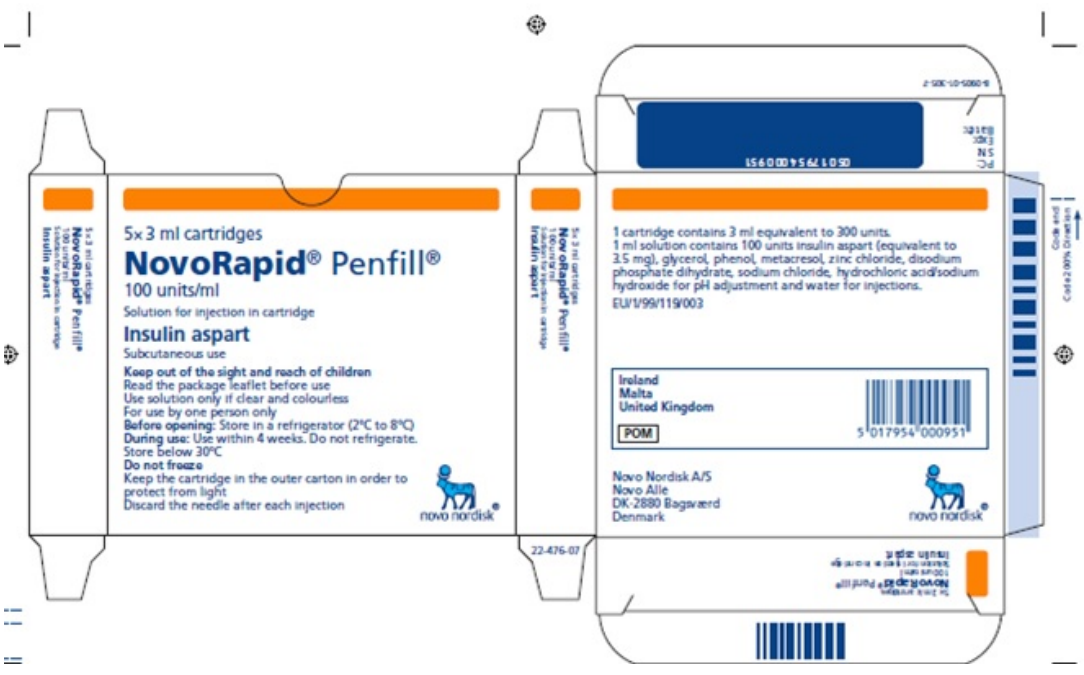
- **Section 2 - What you need to know before you use NovoRapid®**

Skin changes at the injection site
The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (see section 3, How to use NovoRapid®). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

- **Section 4 – Possible side effects**

Skin changes at the injection site: If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect less than 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Outer carton to be supplied



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/ or search for the MHRA Yellow Card app in the Google Play or Apple app Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789.

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.

Company contact point

If you have any questions about this letter or require more information about **NovoRapid® Penfill 100 units/ml solution for injection in cartridge**, please contact Novo Nordisk Medical Information team on 0800 023 2573.

Yours faithfully,

Avideh Nazeri

Dr. Avideh Nazeri MD MBA

Vice President Clinical Development, Medical & Regulatory Affairs (CMR)

Novo Nordisk UK

Adverse events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple app store.
Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes.

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