30 June 2023

COMMUNICATION

NovoMix® 30 FlexPen (insulin aspart) 100units/1ml suspension for injection in pre-filled pen – GB Pack provided to Northern Ireland

Batch number
NT6AG65

Dear Healthcare professional,

Novo Nordisk Ltd would like to inform you that the batch detailed above is a GB specific pack. This was supplied to Northern Ireland in error.

What has happened?

Batch NT6AG65 was sent to Northern Ireland in error. A total of 1512 packs have been supplied (about 1 week of stock).

Why are you being informed?

You may have noticed this error or noticed that the packaging contains GB specific information. We are providing this communication to clarify the situation.

Other than the Marketing Authorisation number and barcode included on the pack this is identical to the packaging currently used on the Northern Ireland market.

What do you need to do?

To minimise disruption to patient supply the MHRA have confirmed this batch may remain on the market.

- The product may be used as normal.
- The product contained is identical and there is no impact on patient safety.

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, SystmOne, Vision, MiDatabank) for healthcare professionals

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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.

Please refer to the Summary of Product Characteristics for NovoMix 30 FlexPen for more information.

Company contact point
If you have any questions about this or require more information please contact Novo Nordisk Customer Care Centre on 0800 023 2573.

Yours faithfully,

Dr Avideh Nazeri MD MBA

Vice President

Clinical Development, Medical & Regulatory Affairs (CMR) UK