Date: 7th February 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

▼ **Refixia® 3000 IU powder and solvent for solution for injection (nonacog beta pegol): Carton printing error**

Dear Healthcare Professional,

Novo Nordisk UK in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

There has been a printing error on the carton for Refixia 3000® IU powder and solvent for solution for injection (nonacog beta pegol) due to missing text.

Summary:

- On one side, the currently approved carton is missing the statement of active substance: 'Powder: 3 000 IU nonacog beta pegol (approx. 750 IU/ml after reconstitution)'
- Although the strength is mentioned on other panels of the carton, the reconstitution information is missing from the carton.
- This currently affects one batch (NS6KS19 – 349 vials) and will apply to GB patients only.

Advice for healthcare professionals:

- Please refer to the Patient Information Leaflet (PIL) inside the package (https://www.medicines.org.uk/emc/product/15459/pil) for the missing information regarding reconstitution.
- Please notify patients who will be using Refixia 3000 IU powder and solvent for solution for injection about the missing information.
- Please ensure that patients are aware of the full reconstitution instructions in the package insert.

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.

Mitigating actions:

- We will correct this and include the missing information in the carton for our next batch run.

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, SystmOne, 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 about Refixia 3000 IU powder and solvent for solution for injection, please contact Novo Nordisk Customer Care Centre on 0800 023 2573.

Yours sincerely,

Dr. Avideh Nazeri

Avideh Nazeri

Digitally signed by Avideh Nazeri
Date: 2024.02.07 10:14:21 Z

Vice President

Clinical Development, Medical and Regulatory Affairs (CMR), Novo Nordisk UK