Rome, 19 August 2024

**IMPORTANT INFORMATION NOTE AGREED WITH THE ITALIAN MEDICINES AGENCY (AIFA)**

**NovoSeven® (eptacog alfa)**

# Communication concerning a shortage of the medicinal product NovoSeven® (eptacog alfa)

Dear Healthcare professional,

Novo Nordisk SpA, in agreement with the European Medicines Agency and the Italian Medicines Agency, would like to inform you of the following:


**Summary**

- A manufacturing issue caused some vials of NovoSeven® 1mg and 2mg to be potentially under-filled, causing the reconstituted final product, to be of lower concentration. This issue affected some products manufactured for Spain, Italy, Latvia, Czechia, Lithuania and Austria. The manufacturing issue has now been resolved.
- This manufacturing issue, combined with release delays from the packaging line and continued capacity constraints which are not related to the manufacturing issue, is expected to cause intermittent shortages of NovoSeven® in all authorized and marketed dosages, at least throughout 2024.
- In a shortage situation, Healthcare Professionals (HCPs) should ensure that patients using NovoSeven® are safely switch to an available alternative strength until supply is restored or to suitable alternatives, if appropriate, based on their clinical judgment and according to the local label recommendations.


**Background**

NovoSeven is a recombinant, activated Factor 7 which is indicated for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in patients with:

- congenital haemophilia with inhibitors to coagulation factors VIII or IX > 5 Bethesda Units (BU);
- congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration;
- acquired haemophilia;
- congenital FVII deficiency;
- Glanzmann's thrombasthenia with past or present refractoriness to platelet transfusions, or where platelets are not readily available;

Severe postpartum haemorrhage: NovoSeven is indicated for the treatment of severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis.

NovoSeven® is available as a powder and solvent for solution for injection in 4 different strengths (1, 2, 5 and 8 mg).

A manufacturing issue on a filling line caused some vials of NovoSeven® 1mg and 2mg to be potentially under-filled. The root cause of the under-filled vial issue has been identified and the filling line will resume operation. NovoSeven® 1 mg and 2 mg can also be filled at an alternative site with some available capacity, but this extra capacity cannot fully cover the main production line. This will result in intermittent shortages

of NovoSeven® in all authorised and marketed dosages, which are expected to last, at least throughout 2024.

As regards the situation in Italy, the product is currently in limited distribution in the following packaging:

- 5 mg (250KUI) powder and solvent for solution for injection (MA n. 029447101): in quota distribution presumably for the whole of 2024 with potential total shortage from 1 August 2024 to 30 September 2024;
- 1 mg (50KUI) powder and solvent for solution for injection (MA n. 029447087), 2 mg (100KUI) powder and solvent for solution for injection (MA n. 029447099) and 8mg (400KUI) powder and solvent for solution for injection (MA n. 029447113): in quota distribution from 4 June 2024 presumably for the whole of 2024.

For any update on the state of shortage, please refer to the List of Medicines in Shortage, which is periodically updated and published at the following link: https://www.aifa.gov.it/farmaci-carenti.

***Recommendation for Risk minimisation***

- In case of emergency, physicians are advised to use another available strength of NovoSeven® or an alternative bypassing agent.
- Use of suitable treatment alternatives to NovoSeven® should only be initiated in consultation with a physician and requires strict medical supervision along with following requirements in the Summary of Product Characteristics.

***Important prescribing information in countries: Spain, Italy, Latvia, Lithuania, Czechia and Austria (usage of potentially under-filled vials)***

- Novo Nordisk's medical evaluation and patient safety assessment of the potential underfilling of some vials of NovoSeven® 1 mg and 2 mg concluded that treatment with under-filled vials will still have therapeutic effect and the probability of serious adverse health consequences is very unlikely. Therefore, the vials can be used as indicated in the NovoSeven label
- The likelihood of a patient receiving an under-filled vial is very low. This is due to extensive manual inspections during production, as a result of which, most under-filled vials were identified and removed before release.
- Based on NovoSeven Summary of Product Characteristics, clinical assessment of response is necessary. When required, repeated dosing is recommended to achieve haemostasis as per the NovoSeven Summary of Product Characteristics.

**Call for reporting**

Adverse events including medication errors relating to NovoSeven® should be reported to the Italian Medicines Agency via the following link https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse and to Novo Nordisk SpA.

**AIFA takes this opportunity to remind all healthcare professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool to confirm a favorable benefit-risk ratio in real conditions of use.**

**Reports of Suspected Adverse Drug Reactions must be sent to the Pharmacovigilance Manager of the Operator's Facility.**

**This Information Note is also published on the AIFA website (https://www.aifa.gov.it/web/guest) whose regular consultation is recommended for the best professional and service information to the citizen.**

**Company contact point**

Further information on drug shortages and medical information can be obtained by contacting Novo Nordisk SpA, Viale Giorgio Ribotta 35/37, 00144 Rome, Italy - +39 06 500881- Website https://www.novonordisk.it/.