RMP Summary

NovoEight®

(turoctocog alfa)

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Disclaimer

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of NovoEight® is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of NovoEight® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic.

Novo Nordisk Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of NovoEight®.

Summary of the risk management plan for NovoEight®

This is a summary of the risk management plan (RMP) for NovoEight®. The RMP details important risks of NovoEight®, how these risks can be minimised and how more information will be obtained about NovoEight®'s risks and uncertainties (missing information).

NovoEight®'s Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how NovoEight® should be used.

This summary of the RMP for NovoEight® should be read in the context of all this information, including the assessment report of the evaluation and its plain-language summary, all which is part of the European public assessment report (EPAR).

Important new concerns or changes to the current ones will be included in updates of NovoEight®'s RMP.

I. The medicine and what it is used for

NovoEight® is authorised for treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency; see the SmPC for the full indication). It contains turoctocog alfa as the active substance and is given by the intravenous route.

Further information about the evaluation of NovoEight®'s benefits can be found in NovoEight®'s EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine's webpage *link to the EPAR summary landing page*: EPAR link

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of NovoEight®, together with measures to minimise such risks and the proposed studies for learning more about NovoEight®'s risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals
- Important advice on the medicine's packaging
- The authorised pack size – the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly

- The medicine's legal status – the way a medicine is supplied to the public (e.g., with or without prescription) can help minimises its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of NovoEight® are risks that need special risk management activities to further investigate or minimise the risk so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of NovoEight®. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g., on the long-term use of the medicine). An overview of important risks and missing information for NovoEight® is provided in the table below.

List of important risks and missing information	
Important identified risks	• Inhibitor development • Allergic/hypersensitivity reactions
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

An overview of important risks for NovoEight® is provided in the table below. No risks are considered to be important potential risks and no information is considered missing.

Important identified risks	
Inhibitor development	
Evidence for linking the risk to the medicine	The formation of neutralising antibodies (inhibitors) to FVIII is a known complication in the management of individuals with haemophilia A. In marketed products, the development of inhibitors (neutralising antibodies) to FVIII has a cumulative incidence of approximately 30−40% and they have mainly been observed in PUP. Inhibitor development is also observed in PUP during Novo Nordisk-sponsored clinical trials with turoctocog alfa.
Risk factors and risk groups	The risk of inhibitor development is highest in PUP. In PUP, the risk of developing inhibitors is highest within the first 50 exposure days. Several patient-related factors have been associated with the risk of developing inhibitors, such as FVIII gene mutation, other genetic factors, family history of inhibitors and ethnicity. Non-genetic risk factors include surgery and intensive treatment.
Risk minimisation measures	*Routine risk minimisation measures:* Routine risk communication: The identified risk of developing inhibitors to FVIII will be addressed in Section 4.8 of the SmPC and Section 4 of the PL. Routine risk minimisation activities recommending specific clinical measures to address the risk: Recommendation for careful monitoring by appropriate clinical observations and laboratory tests is included in the SmPC Section 4.4 and PL Section 2. Other routine risk minimisation measures beyond the Product Information: None *Additional risk minimisation measures:* None
Additional pharmacovigilance activities	*Additional pharmacovigilance activities*: None

Allergic/hypersensitivity reactions	
Evidence for linking the risk to the medicine	Proteins administered intravenously present a potential risk for allergic reactions. Immune reactions to protein drugs can range from being mild to severe life-threatening allergic reactions. Few events of allergic/hypersensitivity reaction were observed in Novo Nordisk-sponsored clinical trials with turoctocog alfa.
Risk factors and risk groups	Patients with a history of allergic reactions or with known hypersensitivity to the active substance, to Chinese hamster proteins or to excipients are at higher risk. The risk of allergic/hypersensitivity reactions is expected to be higher with the initial administrations than with subsequent administrations.
Risk minimisation measures	*Routine risk minimisation measures:* Routine risk communication: The identified risk of allergic/hypersensitivity reactions will be addressed in Section 4.8 of the SmPC and Section 4 of the PL. Hypersensitivity to the active substance or excipients and known allergy to hamster protein are listed as contraindication in Section 4.3 of the SmPC and Section 2 of the PL. Risk minimisation activities in the Product Information beyond routine risk communication: Information on how to detect early signs of allergic/hypersensitivity reactions is included in the SmPC Section 4.4 and Section 2 of the PL. Other routine risk minimisation measures beyond the Product Information: None *Additional risk minimisation measures:* None
Additional pharmacovigilance activities	*Additional pharmacovigilance activities*: None.

Abbreviations: FVIII = factor VIII; PL = package leaflet; PUP = previously untreated patient; rFVIII = recombinant factor VIII; SmPC = Summary of Product Characteristics.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of NovoEight®.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for NovoEight®.