Summary of the risk management plan for eptacog alfa (activated) recombinant coagulation factor VII

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

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

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

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

I. The medicine and what it is used for

NovoSeven is authorised for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures. In addition, NovoSeven is authorised for the treatment of severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis (see SmPC for the full indication). It contains activated recombinant coagulation factor VII (rFVIIa) as the active substance and it is given intravenously.

Further information about the evaluation of NovoSeven's benefits can be found in NovoSeven's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: *EPAR link*.

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

Important risks of NovoSeven, together with measures to minimise such risks and the proposed studies for learning more about NovoSeven'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 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 to minimise 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 periodic safety update report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of NovoSeven is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of NovoSeven 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 NovoSeven. 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).

Following reclassification of safety concerns, there are no important risks or missing information relevant for inclusion in the RMP for NovoSeven (see below).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable, as there are no important risks relevant for inclusion in this RMP for NovoSeven.

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 NovoSeven.

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

There are no other studies required for NovoSeven by the EMA.