Summary of the risk management plan

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

MINIRIN/NOCDURNA/OCTOSTIM's summary of product characteristics (SmPC) and their package leaflets give essential information to healthcare professionals and patients on how they should be used.

I. The medicine and what it is used for

Desmopressin is authorised for central diabetes insipidus, primary nocturnal enuresis, nocturia, renal concentration capacity testing and haematological indications. Desmopressin can be administered via tablets, oral lyophilisate, nasal spray, nasal drops and injection.

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

Important risks of desmopressin, together with measures to minimise such risks and the proposed studies for learning more about desmopressin'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 patient (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 reactions is collected continuously and regularly analysed, 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 desmopressin is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of desmopressin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 desmopressin. 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).

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

II.B Summary of important risks

No important identified/potential risks or missing information are included in the list of safety concerns in the RMP.

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 desmopressin.

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

There are no ongoing or planned additional pharmacovigilance activities for Ferring desmopressin.

The NOCDURNA PASS (000248) was completed with sign-off of the final study report before final sign-off of this RMP version (9.0).