Summary of risk management plan for Desmopressin Orion 60 mcg, 120 mcg and 240 mcg sublingual tablets (desmopressin) Orion Corporation

Date: 15.04.2024, Version 1.2

This is a summary of the risk management plan (RMP) for Desmopressin Orion 60 mcg, 120 mcg and 240 mcg sublingual tablets. The RMP details important risks of Desmopressin Orion, how these risks can be minimized, and how more information will be obtained about Desmopressin Orion's risks and uncertainties (missing information).

Desmopressin Orion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Desmopressin Orion should be used.

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

I. The medicine and what it is used for

Desmopressin Orion is indicated for:

- Central diabetes insipidus.
- Primary nocturnal enuresis in patients from 5 years of age with normal ability to concentrate urine. If efficacy is not observed within one month, treatment should be discontinued, and it may be restarted after six months.
- Symptomatic treatment of nocturia in adults with nocturnal polyuria, i.e. nocturnal urine production exceeds bladder capacity.

It contains desmopressin as the active substance and it is given by mouth as sublingual tablets (see SmPC for the full information).

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

Important risks of Desmopressin Orion, together with measures to minimise such risks and the proposed studies for learning more about Desmopressin Orion'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*.

II.A List of important risks and missing information

Important risks of Desmopressin Orion 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

Safety concerns are adequately addressed in the product information.

The safety information in the product information is aligned to the reference medicinal product.

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 Orion.

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

There are no studies required for Desmopressin Orion.