Part VI: Summary of the risk management plan

Summary of risk management plan for Desmopressin (Desmopressin)

This is a summary of the risk management plan (RMP) for Desmopressin (Desmopressin). The RMP details important risks of desmopressin, how these risks can be minimised, and how more information will be obtained about Desmopressin60 mcg, 120 mcg, 240 mcg sublingual tablets's risks and uncertainties (missing information).

Desmopressin60 mcg, 120 mcg, 240 mcg sublingual tablets's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Desmopressinshould be used.

I. The medicine and what it is used for

Desmopressinis authorised for the treatment of central diabetes insipidus, treatment of primary nocturnal enuresis (from 6 years of age) with a normal ability to concentrate urine, and symptomatic treatment of nocturia in adults, associated with nocturnal polyuria, ie nocturnal urine

production exceeding functional bladder capacity (see SmPC for the full indication). It contains desmopressin as the active substance and it is given oral administration.

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

Important risks of Desmopressin60 mcg, 120 mcg, 240 mcg sublingual tablets, together with measures to minimise such risks and the proposed studies for learning more about Desmopressin60 mcg, 120 mcg, 240 mcg sublingual tablets'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 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 Desmopressinis not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Desmopressinare 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 Desmopressin60 mcg, 120 mcg, 240 mcg sublingual tablets. 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

The safety information in the proposed 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 that are conditions of the marketing authorization or specific obligation of Desmopressin 60 mcg, 120 mcg, 240 mcg sublingual tablets.

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

There are no studies required for the Desmopressin 60 mcg, 120 mcg, 240 mcg sublingual tablets.

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