13 Part VI: Summary of the risk management plan for Desmopressin acetate, 60 µg, 120 µg and 240 µg, Sublingual tablets

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

Desmopressin acetate, sublingual tablets' summary of product characteristics (SmPCs) and its package leaflets gives essential information to healthcare professionals and patients on how desmopressin acetate, sublingual tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the desmopressin acetate, sublingual tablets' RMP.

13.1 Part VI: I. The medicine and what it is used for

Desmopressin acetate, sublingual tablets are authorized for:

For procedure: NL/H/5603/001-003/DC

- Treatment of central diabetes insipidus.
- Treatment of primary nocturnal enuresis in patients from 5 years old, with a normal ability to concentrate urine.
- Symptomatic treatment of nocturia in adults, associated with nocturnal polyuria.

For procedure: NL/H/5604/001-003/DC

- Treatment of central diabetes insipidus.
- Symptomatic treatment of primary nocturnal enuresis in patients from 6 years old, with a normal ability to concentrate urine. The duration of treatment at minimum effective dose determined after dosage adjustment is limited to 3 months, renewable once.
- Symptomatic treatment of nocturia in adults below 65 years of age, associated with nocturnal polyuria.

For procedure: **NL/H/5605/001-003/DC**

- Treatment of central diabetes insipidus.
- Treatment of primary nocturnal enuresis in patients from 5 years old, with a normal ability to concentrate urine.

It contains desmopressin acetate as an active substance and is given orally (sublingual route) as sublingual tablets (60 µg, 120 µg and 240 µg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of desmopressin acetate, sublingual tablets, together with measures to minimize such risks and the proposed studies for learning more about desmopressin acetate sublingual tablets' risks are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflets and SmPCs addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

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

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

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of desmopressin acetate, sublingual tablets are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be 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 acetate, 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).

Table 13-1 List of important risks and missing information

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

13.2.2 Part VI – II.B: Summary of important risks

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

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of desmopressin acetate, sublingual tablets.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for desmopressin acetate, sublingual tablets