PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Desmopressin 60 Mikrogramm Lyophilisat zur sublingualen Anwendung, Desmopressin 120 Mikrogramm Lyophilisat zur sublingualen Anwendung, Desmopressin 240 Mikrogramm Lyophilisat zur sublingualen Anwendung (Desmopressin)

This is a summary of the risk management plan (RMP) for Desmopressin. 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).

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

I. The Medicine and What it is Used For

Desmopressin is authorised for:

Treatment of primary nocturnal enuresis after the age of 5 years after exclusion of organic disorders of the urinary organs.

- As part of an overall therapeutic concept, e.g. when other non-drug therapy measures fail or when drug therapy is indicated, caused by nocturnal ADH deficiency.

- Symptomatic treatment of nocturia (at least 2 nightly urinations) in adults, associated with nocturnal polyuria.

- Traumatic polyuria and polydipsia in the presence of a transient ADH Deficiency after hypophysectomy, after operations in the pituitary gland area or traumatic brain injury.

- Central diabetes insipidus.

It contains desmopressin as the active substance and it is given by sublingual route.

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 public (e.g. with or without

prescription) can help to minimises 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, 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 are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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/use in special patient populations etc.);

Table 4: Part VI.1- Summary of safety concerns

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 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 studies required for desmopressin.