PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR DESMOPRESSIN 360 micrograms/ml ORAL SOLUTION

This is a summary of the risk management plan (RMP) for Desmopressin 360 micrograms/ml oral solution.

Desmopressin 360 micrograms/ml oral solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Desmopressin 360 micrograms/ml oral solution should be used.

I. The medicine and what it is used for

Desmopressin 360 micrograms/ml oral solution is authorized for the treatment of central diabetes insipidus and for the treatment of primary nocturnal enuresis in patients (over 5 years) with normal capacity to concentrate urine (see SmPC for full indication). It contains desmopressin as the active substance, and it is given by oral route.

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

As stated in Part II, no Safety Concerns are associated to the drug product.

Measures to minimise the risks associated to the medicinal product are:

- 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 medicinal product is subject to medical prescription, fact that help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, routine pharmacovigilance activities (ICSRs assessment, literature searches, PSURs and Periodic Signal Detection) ensure that information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary.

According to the EURD List, Desmopressin PSURs must be submitted every 3 years: the last one was submitted in March 2021 (PSUSA/00000964/202012) and next one should be submitted in 2024. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

As stated in Part II, no Important Risks or Missing Information are associated to the drug product.

II.B Summary of important risks

Not applicable

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Desmopressin 360 micrograms/ml oral solution.

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

There are no studies required for Desmopressin 360 micrograms/ml oral solution.