Summary of risk management plan for Tolvaptan Accord 7.5/15/30 mg tablets (Tolvaptan)

This is a summary of the risk management plan (RMP) for Tolvaptan Accord 7.5/15/30 mg tablets. The RMP details important risks of Tolvaptan Accord 7.5/15/30 mg tablets, how these risks can be minimised, and how more information will be obtained about Tolvaptan Accord 7.5/15/30 mg tablets' risks and uncertainties (missing information).

Tolvaptan Accord 7.5/15/30 mg tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tolvaptan Accord 7.5/15/30 mg tablets should be used.

Tolvaptan Accord 7.5/15/30 mg tablets should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Tolvaptan Accord 7.5/15/30 mg tablets' RMP.

I. The medicine and what it is used for

Tolvaptan Accord is indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).
It contains tolvaptan as the active substance and it is given by oral route.
Further information about the evaluation of Tolvaptan Accord 7.5/15/30 mg tablets' benefits can be found in Tolvaptan Accord 7.5/15/30 mg tablets' EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/tolvaptan-accord

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

Important risks of Tolvaptan Accord 7.5/15/30 mg tablets, together with measures to minimise such risks and the proposed studies for learning more about Tolvaptan Accord 7.5/15/30 mg tablets' 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 during, signal management activity, 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 Tolvaptan Accord 7.5/15/30 mg tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tolvaptan Accord 7.5/15/30 mg tablets are 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 Tolvaptan Accord 7.5/15/30 mg 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 (i.e. Pregnancy outcome data);

Important identified risks	• Volume depletion, dehydration and associated sequelae such as renal dysfunction
Important potential risks	• None

Missing Information	• Pregnancy outcome data • Off-label use • Use in hepatic impaired patients

II.B Summary of important risks

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

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 authorization or specific obligation of 'Tolvaptan Accord 7.5/15/30 mg tablets'

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

There are no studies required for 'Tolvaptan Accord 7.5/15/30 mg tablets.