Part VI: Summary of the risk management plan

Summary of risk management plan Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe/ Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion (atosiban acetate)

This is a summary of the risk management plan (RMP) for Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion. The RMP details important risks of Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion, how these risks can be minimised, and how more information will be obtained about Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion's risks and uncertainties (missing information).

Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion's RMP.

I. The medicine and what it is used for

Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion is indicated to delay imminent pre-term birth in pregnant adult women with:

- regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes
- a cervical dilation of 1 to 3 cm (0 3 for nulliparas) and effacement of ≥ 50%
- a gestational age from 24 until 33 completed weeks
- a normal foetal heart rate

It contains atosiban (as acetate) as the active substance and it is given intravenously.

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

Important risks of Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion'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 analysed (including PSUR assessment), 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 Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion 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 Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion. 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).

Important identified risks	• Dyspnoea and Pulmonary oedema
Important potential risks	• Off-label use • Urinary tract infection • Fetal harm
Missing information	• Interaction with other tocolytics, antibiotics and anti-hypertensive agents • Multiple pregnancies • Use in patients < 18 years • Use in patients with hepatic or renal impairment

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 authorization or specific obligation of Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion.

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

The data and conclusions included in this report are confidential and proprietary information of Marketing Authorisation Holder.

There are no studies required for Atosiban Accord 6.75 mg/0.9 ml solution for injection in pre-filled syringe and Atosiban Accord 37.5 mg/5 ml concentrate for solution for infusion.