Part VI: Summary of the risk management plan

Summary of risk management plan for Atropine Accord 0.1mg/ml solution for injection in pre-fillled syringe (Atropine Sulfate)

This is a summary of the risk management plan (RMP) for Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe. The RMP details important risks of Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe risks and uncertainties (missing information).

Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe should be used.

Important new concerns or changes to the current ones will be included in updates of Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe RMP.

I. The medicine and what it is used for

Atropine Accord 0.1 mg/ml, solution for injection in pre-filled syringe is indicated in adults and in paediatric population from birth, but body weight is superior to 3 kg.

As a pre-anaesthetic medication to prevent vagal reactions associated with tracheal stimulation and surgical stimulation. To limit the muscarinic effects of neostigmine, when given postsurgically to counteract non-depolarising muscle relaxant, treatment of hemodynamically compromising bradycardia and/or atrioventricular block due to excessive vagal tone in emergency situation, cardiopulmonary resuscitation; to treat symptomatic bradycardia and AV block, as antidote following overdose or poisoning with acetylcholinesterase inhibitors e.g. anticolinesterases, organophosphorus, carbamates and muscarinic mushrooms.

It contains atropine sulfate as the active substance and it is given by intravenous injection or intramuscular injection.

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

Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe together with measures to minimise such risks and the proposed studies for learning more about Atropine Accord 0.1mg/ml solution for injection in pre-filled syringe 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 and signal management activity, 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 Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely 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 Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe. 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	• 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 authorization or specific obligation of Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe.

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

There are no studies required for Atropine Accord 0.1 mg/ml solution for injection in pre-filled syringe as post-authorisation development plan.