Part VI: Summary of the risk management plan

Summary of risk management plan for Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine)

This is a summary of the risk management plan (RMP) for Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine). The RMP details important risks of Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine), how these risks can be minimised, and how more information will be obtained about Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine)'s risks and uncertainties (missing information).

Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine)'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine) should be used.

Important new concerns or changes to the current ones will be included in updates of Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine)'s RMP.

I. The medicine and what it is used for

Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine) is authorised for symptomatic therapy for poisoning with organophosphorus cholinesterase inhibitors in adults (see SmPC for the full indication). It contains atropine sulfate as the active substance and it is given by intramuscular injection.

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

Important risks of Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine), together with measures to minimise such risks and the proposed studies for learning more about Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine)'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 the case of Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine), these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions 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 N Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine) 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 Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine). 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	Medication error
Missing information	None

II.B Summary of important risks

Important potential risks

Medication error	
Evidence for linking the risk to the medicine	The medicine is intended for use in a specific emergency situation, where poisoning with organophosphate compounds occur (for example pesticides or nerve gasses). The recognition of signs and symptoms of such poisoning can be challenging, but it is crucially important to avoid administering the medicine to a non-intoxicated person or to avoid unnecessary delays in treating the affected person. In an emergency situation in the field, there is often no time for the patient/caregiver to read the patient leaflet in the box and action is required to be immediate. Therefore, it is

	important for the patient/caregiver to be well trained on the signs and symptoms of organophosphate poisoning, the action of atropine and the correct use of the device.
Risk factors and risk groups	All intended users that are dispensed the product as part of an emergency first-aid kit.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2 and 4.4 PIL sections 2 and 3: instructions for use Pack size: One device per pack Prescription only medicine Additional risk minimisation measures: Healthcare professional and patient/caregiver Guide

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 Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine).

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

There are no other studies planned for Atropin actrevo 1,67 mg Injektionslösung im Fertigpen/Atropin actrevo (atropine).