

Part VI: Summary of the risk management plan

Summary of risk management plan for Atropin Abboxia 0.5 mg/ml solution for injection and Atropin Abboxia 1 mg/ml solution for injection (Atropine sulphate)

This is a summary of the risk management plan (RMP) for Atropin Abboxia 0.5 mg/ml solution for injection and Atropin Abboxia 1 mg/ml solution for injection. The RMP details important risks of Atropin Abboxia solution for injection, how these risks can be minimised, and how more information will be obtained about Atropin Abboxia's risks and uncertainties (missing information).

Atropin Abboxia's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Atropin Abboxia should be used.

I. The medicine and what it is used for

Atropin Abboxia, solution for injection (0.5 mg/ml and 1 mg/ml) is authorised for spasmodic contraction in the gastrointestinal tract, salivary hypersecretion, bronchial hypersecretion and/or hypersecretion of gastric juice, bradycardia or preoperative medication (see SmPC for the full indication). It contains atropine sulphate as the active substance and it is given by intravenous or subcutaneous route.

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

There are no identified important risks of Atropin Abboxia, solution for injection.

No specific risk minimisation measures are set beyond the routine risk minimisation measures (contraindications and warnings in the package leaflet and SmPC) for the Atropin Abboxia, solution for injection.

II.A List of important risks and missing information

There are no important risks or missing information for Atropin Abboxia, solution for injection.

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

II.B Summary of important risks

There are no important risks for Atropin Abboxia, solution for injection.

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 Abboxia, solution for injection.

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

There are no studies required for Atropin Abboxia, solution for injection.