Part VI: Summary of the risk management plan

Summary of risk management plan for Dropizol

This is a summary of the risk management plan (RMP) for Dropizol 10mg/ml oral drops. The RMP details important risks of Dropizol, how these risks can be minimised, and how more information will be obtained about Dropizol 10mg/ml oral drops risks and uncertainties (missing information).

Dropizol 10mg/ml oral drops' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Dropizol 10mg/ml oral drops should be used.

Important new concerns or changes to the current ones will be included in updates of Dropizol 10mg/ml oral drops' RMP.

I. The medicine and what it is used for

Dropizol 10mg/ml oral drops is authorised in adults for severe diarrhoea when use of other anti-diarrhoea treatments have not given sufficient effect. Dropizol 10 mg/ml contains Papaver somniferum L., succus siccus (Opium, raw) as the active substance and it is given orally in the form of drops.

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

Important risks of Dropizol 10mg/ml oral drops, together with measures to minimise such risks and the proposed studies for learning more about Dropizol 10mg/ml oral drops' 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*.

II.A List of important risks and missing information

Important risks of Dropizol 10mg/ml oral drops 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 Dropizol 10mg/ml oral drops. Potential risks 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	Dependence and abuse
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk

Dependence and abuse	
Evidence for linking the risk to the medicine	Published literature and many years of use of opioids
Risk factors and risk groups	Prolonged use and/or abuse. Predisposal for drug abuse.
Risk minimisation measures	Routine risk minimisation measures Additional risk minimisation measures: • Restricted prescription (narcotics) and small pack sizes.

Important potential risk
None

Missing information
None

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 Dropizol 10mg/ml oral drops, and thus, this section is not applicable.

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

There are no studies required for Dropizol 10mg/ml oral drops.