

Part VI: Summary of the risk management plan

Summary of risk management plan for Clotrimazole 10 mg/ml ear drops, solution in single-dose container

This is a summary of the risk management plan (RMP) for Clotrimazole 10 mg/ml ear drops, solution in single-dose container (from now on Clotrimazole 10 mg/ml ear drops solution). The RMP details important risks of Clotrimazole 10 mg/ml ear drops solution, and how more information will be obtained about Clotrimazole 10 mg/ml ear drops solution's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Clotrimazole 10 mg/ml ear drops solution is authorised for the treatment of fungal otitis externa (otomycosis) in adults and children (see SmPC for the full indication). It contains clotrimazole as the active substance and it is given by auricular route of administration.

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

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

1.1. II.A List of important risks and missing information

Important risks of Clotrimazole 10 mg/ml ear drops solution 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 Clotrimazole 10 mg/ml ear drops solution . 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	None
Missing information	None

II.B Summary of important risks

There are no important risks associated to Clotrimazole 10 mg/ml ear drops solution, and therefore this section is not applicable.

1.2. II.C Post-authorisation development plan

1.2.1. 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 Clotrimazole 10 mg/ml ear drops solution.

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

There are no studies required for Clotrimazole 10 mg/ml ear drops solution.