

Benzydamine hydrochloride EU-RMP

PART VI- Summary of the risk management plan

Summary of risk management plan for Coldyx lozenge (Benzydamine)

This is a summary of the risk management plan (RMP) for Coldyx lozenge. The RMP details important risks of Coldyx lozenge, and how more information will be obtained about Coldyx's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Coldyx's RMP.

I. The medicine and what it is used for

Coldyx lozenges are indicated for symptomatic local treatment of acute sore throat in adults and children over 6 years of age. It contains benzydamine as the active substance and it is given by oromucosal.

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

Important risks of Coldyx lozenges, together with measures to minimise such risks and the proposed studies for learning more about Coldyx lozenges '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

II.A List of important risks and missing information

Important risks of Coldyx 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

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which there is sufficient proof of a link with the use of Coldyx. 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)

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

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 Coldyx

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

There are no studies required for Coldyx