

## Part VI: Summary of the risk management plan for Coldycof

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

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

### I. The medicine and what it is used for

Coldycof is authorised as cough suppressants, for allergic diseases, especially urticaria, hay fever and allergic rhinitis (see SmPC for the full indication). It contains diphenhydramine as the active substance and it is taken orally.

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

Important risks of Coldycof, together with measures to minimise such risks and the proposed studies for learning more about Coldycof'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.
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These measures constitute *routine risk minimisation* measures.

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

Important risks of Coldycof 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 which there is sufficient proof of a link with the use of Coldycof. 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);

<b>Summary of safety concerns</b>	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

### ***II.B Summary of important risks***

The safety information in the proposed Product Information is aligned to the reference medicinal product.

### ***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 Coldycof.

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

There are no studies required for Coldycof.