



## **PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

### **Summary of risk management plan for Cetirizine Haleon 10 mg film coated tablets**

This is a summary of the risk management plan (RMP) for Cetirizine Haleon 10 mg film coated tablets. The RMP details important risks of cetirizine dihydrochloride, how these risks can be minimised, and how more information will be obtained about cetirizine dihydrochloride's risks and uncertainties (missing information).

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

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

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

Cetirizine dihydrochloride is authorised to be used in adults and children aged 6 years and above:

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis;
- for the relief of symptoms of chronic idiopathic urticaria.

It contains cetirizine dihydrochloride as the active substance, and it is given by oral administration.

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

Important risks of cetirizine dihydrochloride together with measures to minimise such risks and the proposed studies for learning more about cetirizine dihydrochloride'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 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 cetirizine dihydrochloride 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 cetirizine dihydrochloride. 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

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 cetirizine dihydrochloride.

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

There are no studies required for cetirizine dihydrochloride.

## Summary of risk management plan for Cetirizine dihydrochloride Haleon 1 mg/ml oral solution

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

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

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

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

Cetirizine dihydrochloride is authorised to be used in adults and children aged 2 years and above:

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis;
- for the relief of symptoms of chronic idiopathic urticaria.

It contains cetirizine dihydrochloride as the active substance, and it is given by oral administration.

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

Important risks of cetirizine dihydrochloride together with measures to minimise such risks and the proposed studies for learning more about cetirizine dihydrochloride's risks, are outlined below.

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

There are no studies required for cetirizine dihydrochloride.

## Summary of risk management plan for Cetirizine 1 mg/ml oral solution

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

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

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

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

Cetirizine dihydrochloride is authorised to be used in adults and children aged 2 years and above:

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

Important risks of cetirizine dihydrochloride 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 cetirizine dihydrochloride. 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);

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

**II.C Post-authorisation development plan**

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There are no studies which are conditions of the marketing authorisation or specific obligation of cetirizine dihydrochloride.

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

There are no studies required for cetirizine dihydrochloride.