

Part VI: Summary of the risk management plan (RMP) - Betahistine dihydrochloride, 8 mg, 16 mg and 24 mg, Tablets

This is a summary of the RMP for betahistine dihydrochloride, 8 mg, 16 mg and 24 mg, tablets. The RMP details important risks of betahistine dihydrochloride tablets, how these risks can be minimized, and how more information will be obtained about betahistine dihydrochloride tablets' risks and uncertainties (missing information).

Betahistine dihydrochloride tablets' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how betahistine dihydrochloride tablets should be used.

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

13.1 Part VI: I. The medicine and what it is used for

Betahistine is indicated for the treatment of Meniere's syndrome, symptoms of which may include vertigo (often associated with nausea and/or vomiting), tinnitus and hearing loss. It contains betahistine dihydrochloride as the active substance and is given orally as tablets (8 mg, 16 mg and 24 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of betahistine dihydrochloride tablets, together with measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (PSUR) assessment (if applicable)

so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of betahistine dihydrochloride tablets is not yet available, it is listed under ‘missing information’ below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks for betahistine dihydrochloride tablets are risks that need special risk management activities to further investigate or minimize 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 betahistine dihydrochloride tablets. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Hypersensitivity reactions (including anaphylaxis)
Important potential risks	None
Missing information	Use in pediatric population (<18 years of age) Use in pregnancy and lactation

13.2.2 Part VI – II.B: Summary of important risks

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

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of betahistine dihydrochloride, tablets.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for betahistine dihydrochloride, tablets.