Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for CETIRIZINE 10 mg film-coated tablets

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

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

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

I. The Medicine and What It is used for

Cetirizine is authorised in adults and paediatric patients 6 year and above:

- Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria. It contains Cetirizine as the active substance and it is given orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Cetirizine, together with measures to minimise such risks and the proposed studies for learning more about Cetirizine'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 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. 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 9: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• Use in patients with severe renal impairment
Important potential risks	• Use in patients with predisposing factors to urinary retention • Use in patients at risk of convulsions
Missing information	• Use in pregnancy and breastfeeding • Use in children below 6 years of age

II.B Summary of Important Risks

Table 10: Summary of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Important identified risk: Use in patients with severe renal impairment	
Evidence for linking the risk to the medicine	The risk is considered as important identified risk since use in patients with severe renal impairment might lead to the undesirable conditions that require medical care or hospitalization.
Risk factors and risk groups	Patients with severe renal impairment including those on haemodialysis and paediatric patients with renal impairment.
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.2, 4.3 and 5.2. PL sections 2 and 3. Additional risk minimisation measures None
Important potential risk : Use in patients with predisposing factors to urinary retention	
Evidence for linking the risk to the medicine	The risk is considered as important potential risk since it may increase the risk of urinary retention in patients with predisposing factors (male and elderly patients, patients suffering from enlargement of the prostate glands) and thus lead to conditions that require medical care or sometimes

	hospitalization.
Risk factors and risk groups	Patients with predisposing factors to urinary retention, male patients, elderly, patients who have been taking the drug for more than 1 month, concomitant use of indomethacin
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.4. PL section 2. Additional risk minimisation measures None
Important potential risk: Use in patients at risk of convulsions	
Evidence for linking the risk to the medicine	The risk is considered as important potential risk since it might cause seizures or seizure aggravation that require medical care or hospitalization in some cases.
Risk factors and risk groups	Patients with genetic predisposing factors for convulsions, patients with epilepsy and those patients with a history of seizures
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.4. PL section 2. Additional risk minimisation measures None
Missing information: Use in pregnancy and breastfeeding	
Risk minimisation measures	Routine risk minimisation measures SmPC section 4.6. PL section 2. Additional risk minimisation measures None
Missing information: Use in children below 6 years of age	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4, 4.8, 5.1 and 5.2. Additional risk minimisation measures None

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.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Cetirizine.