Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Mometasone Zentiva / Mometasonfuroat Zentiva (mometasone)

This is a summary of the risk management plan (RMP) for Mometasone Zentiva/Mometasonfuroat Zentiva. The RMP details important risks of Mometasone Zentiva/Mometasonfuroat Zentiva, how these risks can be minimised and how more information will be obtained about Mometasone Zentiva/Mometasonfuroat Zentiva's risks and uncertainties (missing information).
Mometasone Zentiva/Mometasonfuroat Zentiva's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mometasone Zentiva/Mometasonfuroat Zentiva should be used.

Important new concerns or changes to the current ones will be included in updates of Mometasone Zentiva/Mometasonfuroat Zentiva's RMP.

I. The medicine and what it is used for

Mometasone Zentiva/Mometasonfuroat Zentiva is authorised for treatment of symptoms of seasonal allergic or perennial rhinitis and further for treatment of nasal polyps (see SmPC for the full indication). It contains mometasone as the active substance and it is given by nasal route.

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

Important risks of Mometasone Zentiva/Mometasonfuroat Zentiva, together with measures to minimise such risks and the proposed studies for learning more about Mometasone Zentiva/Mometasonfuroat Zentiva'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 Mometasone Zentiva/Mometasonfuroat Zentiva are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Mometasone Zentiva/Mometasonfuroat Zentiva. 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	(Class Effects) Possible Systemic and Local Class Effects of Corticosteroids. Hypersensitivity reaction. • Adrenal suppression • Hypersensitivity reactions including anaphylactic reaction • Hyperglycaemia • Eye disorders (cataracts, glaucoma, increased intraocular pressure/ocular hypertension, chorioretinal disorder) • Nasal septum perforation (Class effects) Possible systemic effects of corticosteroids at high doses may include psychological or behavioural disorders. • Psychological or behavioral disorders (psychomotor hyperactivity, sleep disorder, anxiety, depression, aggression [particularly in children])
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 Mometasone Zentiva/Mometasonfuroate Zentiva.

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

There are no studies required for Mometasone Zentiva/Mometasonfuroate Zentiva.