Part VI: Summary of the risk management plan

Summary of risk management plan for Budesonide/formoterol Easyhaler (budesonide, formoterol)

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

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

Important new concerns or changes to the current ones will be included in updates of Budesonide/formoterol Easyhaler's RMP.

I. The medicine and what it is used for

Budesonide/formoterol Easyhaler is authorised for the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β_2-adrenoceptor agonist) is appropriate and additionally for strengths 160/4.5 µg/inhalation and 320/9 µg/inhalation for Chronic Obstructive Pulmonary Disease (COPD) (see SmPC for the full indication). It contains budesonide and formoterol as the active substances and it is given by inhalation.

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

Important risks of Budesonide/formoterol Easyhaler, together with measures to minimise such risks and the proposed studies for learning more about Budesonide/formoterol Easyhaler'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

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Budesonide/formoterol Easyhaler.

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

There are no studies required for Budesonide/formoterol Easyhaler.