Part VI: Summary of the risk management plan

Summary of risk management plan for Beclometason/Formoterol STADA 100 Mikrogramm/ 6 Mikrogramm pro Sprühstoß, Druckgasinhalation, Lösung and Beclometason/Formoterol STADA 200 Mikrogramm/ 6 Mikrogramm pro Sprühstoß, Druckgasinhalation, Lösung (Beclometasone dipropionate and Formoterol fumarate dihydrate)

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

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

Important new concerns or changes to the current ones will be included in updates of Beclometasone/Formoterol STADA's RMP

I. The medicine and what it is used for

Beclometasone/Formoterol STADA 100 micrograms /6 micrograms per actuation pressurized inhalation solution is authorised for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or in patients already adequately controlled on both inhaled corticosteroids and long-acting beta2- agonists.

Also, it is authorised for the treatment of symptoms of severe chronic obstructive pulmonary in patients with severe COPD (FEV1< 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators (see SmPC for the full indication).

Beclometasone/Formoterol STADA 200 micrograms /6 micrograms per actuation pressurized inhalation solution is authorised in adults patients for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or in patients already adequately controlled on both inhaled corticosteroids and long-acting beta2- agonists (see SmPC for the full indication).

Beclometasone/Formoterol STADA contains Beclometasone dipropionate and Formoterol fumarate dihydrate as the active substances and it is given for inhalation.

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

Important risks of Beclometasone/Formoterol STADA, together with measures to minimise such risks and the proposed studies for learning more about Beclometason/Formoterol STADA'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, including PSUR assessment, 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 Beclometasone/Formoterol STADA is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Beclometasone/Formoterol STADA 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 Beclometasone/Formoterol STADA. 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	- ECG QTc prolongation, tachycardia, tachyarrhythmia - Increased risk of Pneumonia in COPD patients
Important potential risks	- Growth retardation (in children and adolescents) when used off-label
Missing information	- Use in pregnancy and lactation - Safety in children aged 5-11 and in adolescents aged 12-17 with asthma when used off-label - Safety in long term use

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 Beclometasone/Formoterol STADA.

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

There are no studies required for Beclometasone/Formoterol STADA.