Part VI: Summary of the risk management plan

Summary of risk management plan for Beclometasone dipropionate and formoterol fumarate dihydrate (100/6)) micrograms per actuation pressurised inhalation solution

This is a summary of the risk management plan (RMP) for Beclometasone dipropionate and formoterol fumarate dihydrate (100/6)) micrograms per actuation pressurised inhalation solution. The RMP details important risks of Beclometasone dipropionate and formoterol fumarate dihydrate (100/6)) micrograms per actuation pressurised inhalation solution and how these risks can be minimised.

Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution should be used.

I. The medicine and what it is used for

Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution is authorised in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta$_2$-agonist) is appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta$_2$-agonist or patients already adequately controlled on both inhaled corticosteroids and long-acting beta$_2$-agonists. And also authorised for symptomatic treatment of 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. It contains Beclometasone dipropionate and formoterol fumarate dihydrate as the active substance and it is for inhalation use.

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

Important risks of Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution are:

- 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 and how to use Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly. The inhalation solution is contained in a pressurised aluminium container sealed with a metering valve and fitted into a polypropylene plastic actuator which incorporates a mouthpiece and is provided with a plastic protective cap.
- Each pack contains 1 pressurised container which provides 120 actuations
- The medicine's legal status — Prescription only medicine.

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 Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution 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 dipropionate and formoterol fumarate dihydrate. 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);

Summary of safety concerns	
Important identified risks	1. Hypokalaemia 2. Adrenal suppression 3. Hyperglycaemia 4. Asthmatic crisis/Paradoxical bronchospasm 5. ECG QTc prolongation, tachycardia, tachyarrhythmia 6. Glaucoma 7. Cataract 8. Atrial fibrillation 9. Granulocytopenia 10. Thrombocytopenia 11. Angina pectoris 12. Psychiatric disorders [Psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes (predominantly in children)] 13. Bone density decreased 14. Cushing's syndrome 15. Angioedema 16. Tremor 17. Pneumonia in patient with COPD
Important potential risks	1. Growth retardation (in children and adolescents) 2. Foetal malformation, tocolytic effect
Missing information	1. Effects in the breast-fed baby 2. Safety in children and adolescent below 17 years of age 3. Use in hepatic/renal impaired patients

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 dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution.

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

There are no studies required for Beclometasone dipropionate and formoterol fumarate dihydrate (100/6) micrograms per actuation pressurised inhalation solution.