Part VI: Summary of the risk management plan

Summary of risk management plan for Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension (Budesonide/Formoterol fumarate dihydrate).

This is a summary of the risk management plan (RMP) for Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension.

Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms 4.5 micrograms per actuation pressurised inhalation, suspension should be used.

I. The medicine and what it is used for

Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension is authorised for symptomatic treatment of patients with COPD with forced expiratory volume in 1 second (FEV1) <70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy is appropriate (see SmPC for the full indication). It contains Budesonide and formoterol fumarate dihydrate 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 fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension together with measures to minimise such risks and the proposed studies for learning more about Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension '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.

II.A List of important risks and missing information

Important risks of Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension 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 Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension. 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	- None
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 Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension.

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

There are no studies required for Budesonide/Formoterol fumarate dihydrate Cipla 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension.