

Part VI: Summary of the risk management plan

Summary of risk management plan for Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung

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. No important risks/safety concerns were identified for Beclometasone dipropionate and formoterol fumarate dihydrate (100/6).

As the relevant sections of this summary apply to all products within this RMP with the same active substance the same RMP part VI is used for all referred products.

The Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung should be used.

I. The medicine and what it is used for

Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung is indicated in 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 patients already adequately controlled on both inhaled corticosteroids and long-acting beta₂-agonists. And also indicated 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

No important risks were identified for Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung.

However, measures to minimise the risks for Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung 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;
- 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

No risks were identified for Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung.

Summary of safety concerns	
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 Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung.

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

There are no studies required for Beclomethason/Formoterol Lupin (100/6) Mikrogramm pro Sprühstoß Druckgasinhalation, Lösung.