SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Ventoline (salbutamol sulfate)

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

Ventoline's Summary of Product Characteristics (SmPC) and its Package Leaflet give essential information to healthcare professionals and patients on how Ventoline should be used.

Important new concerns or changes to the current ones will be included in updates of Ventoline's RMP.

I. The medicine and what it is used for

Ventoline is authorized for treatment or prevention of bronchospasm. It provides short acting bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema. In addition to these indications, the injection/solution for infusion is licensed for the treatment of status asthmaticus and is indicated to arrest uncomplicated labor between 22 and 37 weeks of gestation in patients with no medical or obstetric contraindication to tocolytic therapy, under medical supervision. (see SmPC for the full indication). It contains salbutamol sulfate as the active substance and it is available in many different formulations. These include the pressurized metered-dose inhaler (MDI), dry powder inhaler (DPI), and solution for nebulization (nebules or respirator solution). In addition, salbutamol may also be administered orally (syrups) and by injection/solution for infusion (subcutaneous, intramuscular, intravenous).

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Ventoline, together with measures to minimize such risks and the proposed studies for learning more about Ventoline's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including PSUR assessment 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 Ventoline are risks that need special risk management activities to further investigate or minimize 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 Ventoline. 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

Not applicable.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of Ventoline.

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

There are no studies required for Ventoline.