Summary of risk management plan for Salflumix Easyhaler 50 microg/250 microg/dose inhalation powder 50 microg/500 microg/dose inhalation powder salmeterol and fluticasone propionate

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

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

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

I. The medicine and what it is used for

Salflumix Easyhaler is authorised for the treatment of adult and adolescents patients with asthma. Additionally, the strength 50/500 is used in the treatment of patients with chronic obstructive pulmonary disease (COPD) (see SmPC for the full indication). It contains salmeterol and fluticasone propionate 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 Salflumix Easyhaler, together with measures to minimise such risks and the proposed studies for learning more about Salflumix Easyhaler'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 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 Salflumix Easyhaler is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Salflumix Easyhaler are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Salflumix Easyhaler. 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

Safety concerns are adequately addressed in the proposed product information.

II.C Post-authorisation development plan

There are no studies required for Salflumix Easyhaler.