Summary of risk management plan for Seretide (Salmeterol Xinafoate + Fluticasone Propionate)

This is a summary of the risk management plan (RMP) for Seretide.

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

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

I The medicine and what it is used for

Seretide is authorised for Chronic Obstructive Pulmonary Disease (COPD) and asthma (see SmPC for the full indication). It contains Salmeterol Xinafoate + 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

There are no important risks listed in the Seretide EU-RMP.

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. Information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

III Post-authorisation development plan

III.A Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Seretide.

III.B Other studies in post-authorisation development plan

There are no studies required for Seretide.