## Summary of Risk Management Plan for BiResp Spiromax

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

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

This summary of the RMP should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary as part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of BiResp Spiromax RMP.

## I. The Medicine and What It is used for

BiResp Spiromax is indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2-adrenoceptor agonist) is appropriate, as well as for the symptomatic treatment of patients with severe COPD and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators (see SmPC for the full indication). It contains fixed-dose combination of active substances budesonide and formoterol and it is given as inhalation powder.

Further information about the evaluation of BiResp Spiromax benefits can be found in EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/biresp-spiromax.

## II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of BiResp Spiromax, together with measures to minimise such risks and the proposed studies for learning more about BiResp Spiromax 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, including PSUR assessment, 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 BiResp Spiromax is not yet available, it is listed under 'missing information' below.

## II.A List of Important Risks and Missing Information

Important risks of BiResp Spiromax 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 BiResp Spiromax. 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).

**Table 1: Summary of Safety Concerns**

| **List of important risks and missing information** | |
|---|---|
| **Important identified risks** | • None |
| **Important potential risks** | • None |
| **Missing information** | • None |

## II.B Summary of Important Risks

There are no important risks or missing information for BiResp Spiromax.

## II.C Post-Authorisation Development Plan

### II.C.1 Studies That Are Conditions of the Marketing Authorisation

There are no studies, which are conditions of the marketing authorisation or specific obligation of BiResp Spiromax.

### II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for BiResp Spiromax.