Summary of the risk management plan for Atectura® Breezhaler® (indacaterol/mometasone furoate)

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

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

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

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

I. The medicine and what it is used for

Atectura Breezhaler is authorised for the maintenance treatment of asthma in adults and adolescents 12 years of age and older (see SmPC for the full indication). It contains indacaterol acetate and mometasone furoate as the active substance and it is given by the inhalation of the content of one capsule once-daily using the Breezhaler® inhaler (Concept 1).

Further information about the evaluation of Atectura Breezhaler benefits can be found in Atectura Breezhaler's 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/atectura-breezhaler.

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

Important risks of Atectura Breezhaler together with measures to minimize such risks and the proposed studies for learning more about Atectura Breezhaler'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 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 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 analysed, including Periodic Safety Update Report 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 Atectura Breezhaler are risks that need special risk management activities to further investigate or minimize 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 Atectura Breezhaler. 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.

Table 1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	None
Important potential risks	Serious cardiovascular events
Missing information	None

II B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Table 2 Important potential risk: Serious cardiovascular events

Evidence for linking the risk to the medicine	Current evidence is based on the mechanism of action considerations and class effect information. A causal association with QMF149 has not been established due to lack of adequate statistical or medical evidence of causality in the QMF149 program.
Risk factors and risk groups	Patients with preexisting CCV disease or other CCV risk factors.
Risk minimization measures	Routine risk minimization measures: SmPC section 4.4. Package leaflet Section 2 Additional risk minimization measures: None

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 Atectura Breezhaler.

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

There are no studies required for Atectura Breezhaler.