Part VI: Summary of the risk management plan

Summary of risk management plan for Indacaterol/Glycopyrronium Aurobindo

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

Indacaterol/Glycopyrronium Aurobindo's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Indacaterol/Glycopyrronium Aurobindoshould be used.

Important new concerns or changes to the current ones will be included in updates of Indacaterol/Glycopyrronium Aurobindo's RMP.

I. The medicine and what it is used for

Indacaterol/Glycopyrronium Aurobindois authorised as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)

It contains Indacaterol and glycopyrronium as the active substances and it is given for inhalation of the content of one capsule.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Indacaterol/Glycopyrronium Aurobindo>, together with measures to minimise such risks and the proposed studies for learning more about Indacaterol/Glycopyrronium Aurobindos 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 Indacaterol/Glycopyrronium Aurobindo is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Indacaterol/Glycopyrronium Aurobindo 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 Indacaterol/Glycopyrronium Aurobindo. 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	- Ischemic heart disease - Tachyarrhythmias - Atrial fibrillation
Important potential risks	- Cardiac arrhythmias (bradyarrhythmias, conduction abnormalities, ectopies, cardiac repolarization abnormalities, sudden death, non-specific cardiac arrhythmias) - Intubation, hospitalization and death due to asthma related events in asthma population (off-label use) - QTc prolongation and Interaction with drugs prolonging QT interval - Myocardial infarction - Cardiac failure - Cerebrovascular events
Missing information	- Use in pregnancy and lactation

II.B Summary of important risks

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

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Indacaterol/glycopyrronium.

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

There are no studies required for Indacaterol/glycopyrronium.