Part VI: Summary of the risk management plan

Summary of risk management plan for Ipratropium bromide/salbutamol Neutec 0.5 mg /2.5 mg nebuliser solution (ipratropium bromide / salbutamol sulphate)

This is a summary of the risk management plan (RMP) for Ipratropium bromide/salbutamol Neutec 0.5 mg /2.5 mg nebuliser solution. The RMP details important risks of Ipratropium bromide/salbutamol Neutec how these risks can be minimised, and how more information will be obtained about Ipratropium bromide/salbutamol Neutec's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Ipratropium bromide/salbutamol Neutec is indicated in the routine maintenance treatment of chronic obstructive pulmonary disease (COPD), in patients who require treatment with more than one bronchodilator.
(see SmPC for the full indication). It contains ipratropium bromide and salbutamol sulphate 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 Ipratropium bromide/salbutamol Neutec, together with measures to minimise such risks and the proposed studies for learning more about Ipratropium bromide/salbutamol Neutec's risks, are outlined below.

II.A List of important risks and missing information

Important risks of Ipratropium bromide/salbutamol Neutec are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by inhalation. 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 Ipratropium bromide/salbutamol Neutec. 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

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

Not applicable

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

Not applicable