PART VI: Summary of the risk management plan

Please note that TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule is different brand name of the same medicinal product with the identical SmPC. As the safety concerns and their management including planned pharmacovigilance activities, as well as indications, posology, target population and other information are identical for the product covered by this RMP.

Summary of risk management plan for TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule

This is a summary of the risk management plan (RMP) for TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule. The RMP details important risks of TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule, how these risks can be minimised, and how more information will be obtained about TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule risks and uncertainties (missing information).

TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule summary of product characteristics (SmPC) and its package leaflet give essential information to

healthcare professionals and patients on how TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule should be used.

Important new concerns or changes to the current ones will be included in updates of TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule RMP.

I. The medicine and what it is used for

TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule is authorised for the treatment of symptoms in patients suffering from chronic obstructive pulmonary disease (see SmPC for the full indication). It contains tiotropium bromide monohydrate as the active substance and it is intended for inhalation use only.

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

Important risks of TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule together with measures to minimise such risks and the proposed studies for learning more about TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule 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, 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 TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule 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 TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule. 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

There are no studies which are conditions of the marketing authorisation or specific obligation of TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule.

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

There are no studies required for TIOTROPIUM BROMIDE MONOHYDRATE 18 microgram inhalation powder, hard capsule.