Part VI: Summary of the risk management plan

Summary of risk management plan for Tiolair/Scinorus/Tiotraxa 7 micrograms, inhalation powder, hard capsule (Tiolair/Scinorus/Tiotraxa)

This is a summary of the risk management plan (RMP) for Tiolair/Scinorus/Tiotraxa. The RMP details important risks of Tiolair/Scinorus/Tiotraxa and how more information will be obtained about Tiolair/Scinorus/Tiotraxa's risks and uncertainties (missing information).

Tiolair/Scinorus/Tiotraxa's summary of product characteristics (SmPC) and its package leaflet (PL) containing Instructions for handling and use give essential information to healthcare professionals and patients on how Tiolair/Scinorus/Tiotraxa should be used.

Important new concerns or changes to the current ones will be included in updates of Tiolair/Scinorus/Tiotraxa's RMP.

I. The medicine and what it is used for

Tiolair/Scinorus/Tiotraxa is indicated in adults for maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstruction pulmonary disease (COPD) (see SmPC for the full indication). It contains TIOTROPIUM BROMIDE as the active substance and it is given by inhalation.

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

Important risks of Tiolair/Scinorus/Tiotraxa together with measures to minimise such risks and the proposed studies for learning more about Tiolair/Scinorus/Tiotraxa, 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*.

In the case of Tiolair/Scinorus/Tiotraxa, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.
If important information that may affect the safe use of Tiolair/Scinorus/Tiotraxa is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tiolair/Scinorus/Tiotraxa 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 Tiolair/Scinorus/Tiotraxa. 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	• Cardiac mortality • Cardiac disorders (ischaemic heart disease including myocardial infarction and angina pectoris, cardiac arrhythmia, cardiac failure,). • Medication errors (including inappropriate schedule of product administration and wrong technique in product usage process)
Missing information	• Pregnant and breast-feeding women • Patients with a recent history of myocardial infarction, unstable or life-threatening cardiac arrhythmia, paroxysmal tachycardia and decompensated heart failure

II.B Summary of important risks

According to the EU RMP template accompanying GVP Module V Rev.2 (3), for hybrid application products such as the Applicant's Tiolair/Scinorus/Tiotraxa, in this section only safety concerns with additional risk minimisation activities or additional pharmacovigilance activities need to be included.

Important potential risks	
Medication error (including inappropriate schedule of product administration and wrong technique in product usage process)	
Risk minimisation measures	Routine risk minimisation measures • Summary of product characteristics (SmPC): section 4.2 Posology and method of administration - Instructions for handling and use. Special warnings and instructions are included in each step to drawn attention of the patient for the correct use of the device. • Package leaflet (PL): Vertical-Haler instructions for use. Special warnings and instructions are included in each step to drawn attention of the patient for the correct use of the device. • TIOLAIR/SCINORUS/TIOTRAXA is subject to medical prescription. Additional risk minimisation measures: • Guide for healthcare professionals (HCPs)

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 Tiolair/Scinorus/Tiotraxa.

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

There are no studies required for Tiolair/Scinorus/Tiotraxa.