# PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

## PART VI.1 SUMMARY OF RISK MANAGEMENT PLAN FOR SPIOLTO RESPIMAT (TIOTROPIUM BROMIDE + OLODATEROL)

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

Spiolto Respimat's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Spiolto Respimat should be used.

Important new concerns or changes to the current ones will be included in updates of Spiolto Respimat's RMP.

### I. THE MEDICINE AND WHAT IT IS USED FOR

Spiolto Respimat is authorised for chronic obstructive pulmonary disease (see SmPC for the full indication). It contains tiotropium bromide + olodaterol 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 Spiolto Respimat, together with measures to minimise such risks and the proposed studies for learning more about Spiolto Respimat's 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. This regular analysis includes compilation and assessment of PSURs. All of these measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Spiolto Respimat is not yet available, it is listed under 'missing information' below.

## II.A List of important risks and missing information

Important risks of Spiolto Respimat are risks that need special risk management activities to further investigate or minimise 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 Spiolto Respimat. 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 disorders (ischaemic heart disease, cardiac arrhythmia, cardiac failure, cardiac mortality)[1,2]<br>Off-label use in asthma[2] |
| Missing information | Long-term data beyond 1 year of use (adverse cardiovascular outcome)[2]<br>Pregnant and breast-feeding women[1,2]<br>Patients with a recent history of:<br>• Myocardial infarction[1,2]<br>• Unstable or life-threatening cardiac arrhythmia[1,2]<br>• Paroxysmal tachycardia[1,2]<br>• Decompensated heart failure[1,2] |

[1] Risk derived from mono substance tiotropium
[2] Risk derived from mono substance olodaterol

## II.B Summary of important risks

PVI.Table 1 Important potential risks

| | |
|---|---|
| **Cardiac disorders (ischaemic heart disease, cardiac arrhythmia, cardiac failure, cardiac mortality)** | |
| Risk minimisation measures | *Routine risk minimisation measures*SmPC Sections 4.4, 4.8, and 4.9.<br>PL Section 4. |
| **Off-label use in asthma** | |
| Risk minimisation measures | *Routine risk minimisation measures*<br>SmPC Sections 4.4.<br>PL Section 2. |

PVI.Table 2 Missing information

| | |
|---|---|
| **Long-term data beyond 1 year of use (adverse cardiovascular outcome)** | |
| Risk minimisation measures | *Routine risk minimisation measures*<br>None. |
| **Pregnant and breast-feeding women** | |
| Risk minimisation measures | *Routine risk minimisation measures*<br>SmPC Section 4.6.<br>PL Section 2. |
| **Patients with a recent history of myocardial infarction, unstable or life-threatening cardiac arrhythmia, paroxysmal tachycardia, decompensated heart failure** | |
| Risk minimisation measures | *Routine risk minimisation measures*<br>SmPC Section 4.4. |

## 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 Spiolto Respimat.

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

There are no studies required for Spiolto Respimat.

## ABBREVIATIONS

| | |
|---|---|
| PL | Package Leaflet |

| | |
|---|---|
| PSUR | Periodic Safety Update Report |
| RMP | Risk Management Plan |
| SmPC | Summary of Product Characteristics |