

## Part VI: Summary of the risk management plan

### *Summary of risk management plan for Ambrisentan Olpha*

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

Ambrisentan Olpha summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ambrisentan Olpha should be used.

Important new concerns or changes to the current ones will be included in updates of Ambrisentan Olpha's RMP

#### ***I. The medicine and what it is used for***

Ambrisentan Olpha is authorised for the treatment of pulmonary arterial hypertension (see SmPC for the full indication). It contains ambrisentan as the active substance and it is given orally.

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

Important risks of Ambrisentan Olpha together with measures to minimise such risks and the proposed studies for learning more about Ambrisentan Olpha'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 the case of Ambrisentan Olpha, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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.

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

Important risks of Ambrisentan Olpha 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 Ambrisentan Olpha. 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);

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"><li>– Teratogenicity</li><li>– Decreased haemoglobin/haematocrit, anaemia, including anaemia requiring transfusion</li><li>– Hepatotoxicity</li></ul>

<b>List of important risks and missing information</b>	
Important potential risks	– Testicular tubular atrophy/ male infertility
Missing information	– None

## *II.B Summary of important risks*

### *Important identified risks*

<b>Important identified risk of teratogenicity</b>	
Risk minimisation measures	Routine risk minimisation measures: <ul style="list-style-type: none"> <li>– Routine risk communication in SmPC sections 4.2, 4.3, 4.4, 4.6 and 5.3 and PIL section 2.</li> <li>– Prescription medicine only</li> </ul> Additional risk minimisation measures <ul style="list-style-type: none"> <li>– Educational materials for physicians and patients: <b>Patient reminder card</b></li> </ul>

<b>Important identified risk of hepatotoxicity</b>	
Risk minimisation measures	Routine risk minimisation measures: <ul style="list-style-type: none"> <li>• Routine risk communication in SmPC sections 4.2, 4.3, 4.4, 4.8, 5.1 and 5.2 and PIL section 2 and 4.</li> <li>• Prescription medicine only</li> </ul> Additional risk minimisation measures <ul style="list-style-type: none"> <li>• Educational materials for physicians and patients: <b>Patient reminder card</b></li> </ul>

## *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 Ambrisentan Olpha.

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

There are no studies required for Ambrisentan Olpha.