

## Part VI: Summary of the risk management plan

### Summary of risk management plan for <Product name> 267 mg, 534 mg, 801 mg film-coated tablet (Pirfenidone)

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

<Product name>'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <Product name> should be used.

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

<Product name> is authorised for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF) in adults (see SmPC for the full indication). It contains pirfenidone 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 <Product name>, together with measures to minimise such risks and the proposed studies for learning more about <Product name>'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 <Product name>, 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, including PSUR assessment 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 <Product name> is not yet available, it is listed under ‘missing information’ below.

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

Important risks of <Product name> 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 <Product name>. 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>Summary of safety concerns</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Photosensitivity reaction and rash</li> <li>• DILI</li> <li>• Gastrointestinal symptoms</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Severe skin reactions</li> <li>• Risk of medication error in patients transferring between capsules and tablets</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• QT Prolongation</li> <li>• Underlying specific cardiac events</li> </ul>

**II.B Summary of important risks**

<b>Important identified risk: Photosensitivity reaction and rash</b>	
Risk minimisation measures	<p><b>Routine risk minimisation measures:</b> Covered under the following section of SmPC: 4.2, 4.4, 4.8. Advice to patients in PL (PL sections 2 and 4).</p> <p><b>Other routine risk minimisation measures:</b> Restricted medical prescription.</p> <p><b>Additional risk minimisation measure(s):</b> Safety Checklist.</p>
Additional pharmacovigilance activities	<p><b>Additional pharmacovigilance activities:</b> None.</p>

<b>Important identified risk: DILI</b>	
Risk minimisation measures	<p><b>Routine risk minimisation measures:</b> Covered under the following section of SmPC: 4.2, 4.3, 4.4, 4.8. Advice to patients in PL (PL sections 2 and 4).</p> <p><b>Other routine risk minimisation measures:</b> Restricted medical prescription.</p> <p><b>Additional risk minimisation measure(s):</b> Safety Checklist.</p>
Additional pharmacovigilance activities	<p><b>Additional pharmacovigilance activities:</b> None.</p>

### ***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 <Product name>.

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

There are no studies required for <Product name>.