## Part VI: Summary of the risk management plan

### Summary of risk management plan for Pirfenidone 267 mg hard capsules

This is a summary of the risk management plan (RMP) for Pirfenidone 267 mg hard capsules (hereinafter referred to as pirfenidone). The RMP details important risks of pirfenidone, how these risks can be minimised, and how more information will be obtained about pirfenidone's risks and uncertainties (missing information).

Pirfenidone's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on pirfenidone should be used.

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

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

Pirfenidone is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF). (See SmPC for the full indication). It contains pirfenidone as the active substance and is given orally.

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

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

In addition to these measures, information about the 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 pirfenidone 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 pirfenidone. 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** | Photosensitivity reaction and rash |
| | Drug induced Liver injury (DILI) |
| **Important potential risks** | None |
| **Missing information** | None |

## II.B Summary of important risks

| **Important identified risks: Photosensitivity reaction and rash** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Listings in SmPC section, 4.2 Posology and method of administration, 4.4 Special warnings and precautions for use. 4.8 Undesirable effects.<br>Listings in PIL section 2. What you need to know before you take the Pirfenidone and 4 Possible side effects.<br>Other routine risk minimisation measures beyond the Product Information:<br>Medicine's legal status: Pirfenidone is a prescription only medicine.<br>Pack size: Blister packs 63 252 270 capsule, hard<br>Additional Risk Minimization Measures:<br>• Safety Checklist<br>• The SmPC<br>• The PIL |
| Additional pharmacovigilance activities | Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:<br>AE follow-up form for adverse Reaction<br>Additional pharmacovigilance activities:<br>None |

| **Important identified risk: Drug induced Liver injury (DILI)** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Listings in SmPC section, 4.2 Posology and method of administration, 4.4 Special warnings and precautions for use, 4.3 Contraindications, 4.8 Undesirable effects and 5.2 Pharmacokinetic properties<br>Listings in PIL section 2. What you need to know before you take the pirfenidone, 3. How to take pirfenidone and 4 Possible side effects.<br>Other routine risk minimisation measures beyond the Product Information:<br>Medicine's legal status: Pirfenidone is a prescription only medicine.<br>Pack size: Blister packs 63, 252, and 270 capsules, hard<br>Additional risk minimisation measures:<br>• Safety Checklist<br>• The SmPC<br>• The PIL |
| Additional pharmacovigilance activities | Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:<br>AE follow-up form for adverse Reaction<br>Additional pharmacovigilance activities:<br>None |

## 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 pirfenidone.

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

There are no studies required for pirfenidone.