Summary of risk management plan for Pirfenidone

This is a summary of the risk management plan (RMP) for Pirfenidone film-coated tablets. 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 how pirfenidone should be used.

This summary of the RMP for Pirfenidone film-coated tablets should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which is part of the European Public Assessment Report (EPAR).

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 film-coated tablets is authorised for the treatment of mild to moderate idiopathic pulmonary fibrosis in adults (see SmPC for the full indication). It contains pirfenidone as the active substance and it is given by oral route.
Further information about the evaluation of pirfenidone’s benefits can be found in pirfenidone’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage https://www.ema.europa.eu/en/medicines/human/summaries-opinion/pirfenidone-aet

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 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 case of pirfenidone, 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 pirfenidone is not yet available, it is listed under ‘missing information’ below.

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);

Summary of safety concerns	
Important identified risks	• Photosensitivity and rash • Drug-induced liver injury (DILI) • Gastrointestinal symptoms
Important potential risks	• Severe skin reactions
Missing information	• QT Prolongation • Underlying specific cardiac events

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important identified risk: *Photosensitivity and* rash	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.2, 4.4 and 4.8* *PIL Section: 2. and 4.* Pirfenidone is available by restricted prescription only. Additional risk minimisation measures: *Prescribers safety checklist*

Important identified risk: Drug induced liver injury	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section: 4.2, 4.3, 4.4, and 4.8* *PIL Section: 2.* Pirfenidone is available by restricted prescription only. Additional risk minimisation measures: *Prescribers safety checklist*

Important identified risk: Gastrointestinal symptoms	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.2, and 4.8* *PIL Section: 4* Pirfenidone is available by restricted prescription only. Additional risk minimisation measures:

Important potential risks: Severe skin reactions	
Risk minimisation measures	Routine risk communication: *SmPC section: 4.4 and 4.8* *PIL Section: 2 and 4* Pirfenidone is available by restricted prescription only Additional risk minimisation measures: *None*

Missing information: QT Prolongation	
Risk minimisation measures	Routine risk communication: *SmPC section: NA* *PIL Section: NA* Pirfenidone is available by restricted prescription only Additional risk minimisation measures: *None*

Missing information: Underlying specific cardiac events	
Risk minimisation measures	Routine risk communication: *SmPC section: NA* *PIL Section: NA* Pirfenidone is available by restricted prescription only Additional risk minimisation measures: *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.