13 Part VI: Summary of the risk management plan for Pirfenidone, 267 mg and 801 mg, Film-coated tablets

This is a summary of the risk management plan (RMP) for pirfenidone, 267 mg and 801 mg, film-coated tablets. The RMP details important risks of pirfenidone, film-coated tablets, how these risks can be minimized and how more information will be obtained about pirfenidone, film-coated tablet's risks and uncertainties (missing information).

Pirfenidone, film-coated tablet's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how pirfenidone, film-coated tablets should be used.

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

13.1 Part VI: I. The medicine and what it is used for

Pirfenidone, film-coated tablets are authorized for:

Pirfenidone is indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

It contains pirfenidone as an active substance and is given orally as film-coated tablets (267 mg and 801 mg).

13.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of pirfenidone, film-coated tablets, together with measures to minimize such risks and the proposed studies for learning more about pirfenidone, film-coated tablets risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In the case of pirfenidone, film-coated tablets, these measures are supplemented with *additional risk minimization measures* mentioned under relevant important identified risks below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment (if applicable) 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 pirfenidone, film-coated tablets is not yet available, it is listed under 'missing information' below.

13.2.1 Part VI – II.A: List of important risks and missing information

Important risks of pirfenidone, film-coated tablets are risks that need special risk management activities to further investigate or minimize 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, film-coated tablets. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Photosensitivity reaction and rash
	Drug induced liver injury (DILI)
	Gastrointestinal (GI) symptoms
Important potential risks	Severe skin reactions
	Risk of medication error in patients transferring between capsules and tablets
Missing information	QT prolongation
	Underlying specific cardiac events

13.2.2 Part VI – II.B: Summary of important risks

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

Table 13-2 Important identified risk: Photosensitivity reaction and rash

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.2, 4.4 and 4.8 PL sections 2, 3 and 4 Legal status: Prescription only **Additional risk minimization measures** • Safety checklist for prescribing physician

Table 13-3 Important identified risk: DILI

Risk minimization measures	**Routine risk minimization measures:** SmPC sections 4.2, 4.3, 4.4 and 4.8 PL sections 2, 3 and 4 Legal status: Prescription only **Additional risk minimization measures** • Safety checklist for prescribing physician

13.2.3 Part VI – II.C: Post-authorization development plan

13.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of pirfenidone, film-coated tablets.

13.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for pirfenidone, film-coated tablets.