Part VI: Summary of the risk management plan

Summary of risk management plan for [Product name]

This is a summary of the risk management plan (RMP) for 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 how 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 authorised in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF) (see SmPC for the full indication). It contains pirfenidone, as the active substance, and it is given by oral route of administration of 267 mg, and 801 mg film-coated tablets.

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 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 adverse reactions is collected continuously and regularly analysed, 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 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 administered. 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 • Gastrointestinal 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

II.B Summary of important risks

Photosensitivity reaction and rash **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: Recommendation for dose modification in section 4.2 of the SmPC. Warning in section 4.4 of the SmPC that cautions against direct exposure to sunlight. Listed under section 4.8 of the SmPC as a very common undesirable effect. – Prescription only medicine.

	Additional risk minimisation measures: • *Educational programme for physicians*

DILI **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: Section 4.2 (Posology and method of administration) of the SmPC. Section 4.3 (Contraindications) of the SmPC. Warning in section 4.4 of the SmPC that cases of severe DILI, including isolated cases with fatal outcome, have been reported post-marketing. Listed under section 4.8 of the SmPC as an uncommon undesirable effect. – Prescription only medicine. Additional risk minimisation measures: • *Educational programme for physicians*

Gastrointestinal symptoms **Important identified risk**	
Risk minimisation measures	Routine risk minimisation measures: Advice in section 4.2 of the SmPC regarding method of administration that pirfenidone is to be taken orally with food in patients who experience intolerance due to GI side effects. Listed under section 4.8 of the SmPC as very common and common undesirable effects. – Prescription only medicine. Additional risk minimisation measures: *None*

Severe skin reactions **Important potential risk**	
Risk minimisation measures	Routine risk minimisation measures:

	Section 4.4 (Special warnings and precautions for use) of the SmPC. Section 4.8 (Undesirable effects) of the SmPC. – Prescription only medicine. Additional risk minimisation measures: *None*

Risk of medication error in patients transferring between capsules and tablets **Important potential risk**	
Risk minimisation measures	Routine risk minimisation measures: Section 3 (Pharmaceutical Form) of the SmPC. (Colours of the tablets are the different by strengths: yellow, orange and brown). – Prescription only medicine. Additional risk minimisation measures: *None*

QT prolongation **Missing information**	
Risk minimisation measures	Routine risk minimisation measures: Currently risk minimization measures for this missing information are not addressed in the SmPC. – Prescription only medicine. Additional risk minimisation measures: *None*

Underlying specific cardiac events **Missing information**	
Risk minimisation measures	Routine risk minimisation measures: Currently risk minimization measures for this missing information are not addressed in the SmPC. – Prescription only medicine.

	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.