Part VI: Summary of the risk management plan

Summary of risk management plan for Pirfenidone Accord (pirfenidone)

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

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

Important new concerns or changes to the current ones will be included in updates of Pirfenidone Accord's RMP.

I. The medicine and what it is used for

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

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 Pirfenidone Accord, together with measures to minimise such risks and the proposed studies for learning more about Pirfenidone Accord'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 Accord, 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 signal management activity, 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 Accord 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 Accord. 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);

Important identified risks	• Photosensitivity reaction and rash • Drug-induced liver injury
Important potential risks	• None
Missing information	• None

II.B Summary of important risks with additional risk minimisation measures

Important Identified Risks: **Photosensitivity reaction and rash**	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> • SmPC sections 4.2, 4.4 and 4.8 • PIL sections 2 and 4 • Patients experiencing a mild to moderate photosensitivity reaction or rash should be reminded to use a sunblock daily and avoid

	exposure to the sun. Patients should be instructed to report symptoms of photosensitivity reaction or rash to their physician, is included in section 4.2 and 4.4 of SmPC and section 2 of PIL • Dose adjustments or treatment discontinuation should be practised by physician in mild to severe cases of photosensitivity reactions/rash, is included in SmPC section 4.2 and 4.4 and PIL section 3. • Prescription only status of the product Additional risk minimisation measures: Safety checklist for prescribing physician
Important Identified Risks: **Drug-induced liver injury**	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.3, 4.4 and 4.8 • PIL section 2 and 4 • Contraindication in severe hepatic impairment or end stage liver disease, is included in SmPC section 4.3. • Recommendation to perform regular monitoring of liver function tests (ALT, AST and bilirubin) prior to the initiation of Pirfenidone treatment with and subsequently at monthly intervals for the first 6 months and then every 3 months thereafter is mentioned in SmPC sections 4.4.

	• Recommendation that prompt clinical evaluation and measurement of liver function tests should be performed in patients who report symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice is included in section 4.4 of SmPC. • Monitor the patient closely, if a patient exhibits an aminotransferase elevation > 3 to < 5 × ULN without bilirubin elevation and without symptoms or signs DILI after starting Pirfenidone. Instruction for discontinuation of other medicines associated with liver toxicity along with treatment stopped and re-initiate are mentioned in SmPC section 4.4. • Prescription only status of the product <u>Additional risk minimisation measures:</u> Safety checklist for prescribing physician

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 Accord.

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

There are no studies required for Pirfenidone Accord.