Part VI: Summary of the risk management plan

Summary of risk management plan for Pirfenidone Accord 267 mg/801 mg Tablets (pirfenidone)

This is a summary of the risk management plan (RMP) Pirfenidone Accord 267 mg/801 mg Tablets. The RMP details important risks of Pirfenidone Accord 267 mg/801 mg Tablets, how these risks can be minimised, and how more information will be obtained about Pirfenidone Accord 267 mg/801 mg Tablets' risks and uncertainties (missing information).

Pirfenidone Accord 267 mg/801 mg Tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pirfenidone Accord 267 mg/801 mg Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Pirfenidone Accord 267 mg/801 mg Tablets' 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 267 mg/801 mg Tablets, together with measures to minimise such risks and the proposed studies for learning more about Pirfenidone Accord 267 mg/801 mg Tablets' 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 267 mg/801 mg Tablets, 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.

If important information that may affect the safe use of Pirfenidone Accord 267 mg/801 mg Tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Pirfenidone Accord 267 mg/801 mg Tablets 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 267 mg/801 mg 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);

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 with additional risk minimisation measures

Important Identified Risks: **Photosensitivity reaction and rash**	
Risk minimisation measures	Routine risk minimisation measures: Sections 4.2, 4.4 and 4.8 of Pirfenidone Accord SmPC and corresponding sections of PIL have information on this safety concern. Other routine risk minimisation measures include; the labelling and the 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: Sections 4.4 and 4.8 of Pirfenidone Accord SmPC and corresponding sections of PIL have information on this safety concern Other routine risk minimisation measure includes the prescription only status of the product. Additional risk minimisation measures: 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 267 mg/801 mg Tablets.

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

There are no studies required for Pirfenidone Accord 267 mg/801 mg Tablets.