Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Pirfenidone Glenmark 267mg and 801 mg film-coated tablets (Pirfenidone)

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

Pirfenidone Glenmark 267mg and 801 mg film-coated tablets' Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Pirfenidone Glenmark 267mg and 801 mg film-coated tablets should be used.

I. The medicine and what it is used for

Pirfenidone Glenmark 267mg and 801 mg film-coated tablets is authorised in adults for the treatment of idiopathic pulmonary fibrosis (IPF).

It contains Pirfenidone as the active substance and it is given by orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Pirfenidone Glenmark 267mg and 801 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Pirfenidone Glenmark 267mg and 801 mg film-coated 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 PL 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 Glenmark 267mg and 801 mg film-coated 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 Periodic Safety Update Report (PSUR) assessment if PSUR is required by Health Authority, 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 Glenmark 267mg and 801 mg film-coated 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 Glenmark 267mg and 801 mg 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).

List of Important Risks and Missing Information	
Important identified risk(s)	• Photosensitivity reaction and rash • Drug induced liver injury
Important potential risk(s)	• None
Missing information	• None

II.B. Summary of important risk

Important Identified Risk – Photosensitivity reaction and rash	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.2: Posology and method of administration • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take Pirfenidone • Section 3: How to take Pirfenidone • Section 4: Possible side effects Additional risk minimisation measures: Physician information (safety checklists)

Important Identified Risk – Drug induced liver injury	
Risk minimisation measures	Routine risk minimisation measures:

Important Identified Risk – Drug induced liver injury	
	The information regarding this safety concern is mentioned in the following section(s): **SmPC:** • Section 4.2: Posology and method of administration • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 2: What you need to know before you take Pirfenidone • Section 3: How to take Pirfenidone • Section 4: Possible side effects <u>Additional risk minimisation measures:</u> Physician information (safety checklists)

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 Glenmark 267mg and 801 mg film-coated tablets.

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

There are no studies required for Pirfenidone Glenmark 267mg and 801 mg film-coated tablets.