Part VI: Summary of the risk management plan

Summary of risk management plan for PIRFENIDONE SANDOZ, FREDALIX AND PIRFENAIR (pirfenidone)

This is a summary of the RMP for Pirfenidone Sandoz, Fredalix and Pirfenair. The RMP details important risks of Pirfenidone Sandoz, Fredalix and Pirfenair, how these risks can be minimized, and how more information will be obtained about Pirfenidone Sandoz, Fredalix and Pirfenair risks and uncertainties (missing information).

Pirfenidone Sandoz, Fredalix and Pirfenair Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Pirfenidone Sandoz, Fredalix and Pirfenair should be used.

Important new concerns or changes to the current ones will be included in updates of Pirfenidone Sandoz, Fredalix and Pirfenair RMP.

I. The medicine and what it is used for

Pirfenidone Sandoz, Fredalix and Pirfenair are authorized for indications outline below:

Pirfenidone Sandoz, Fredalix and Pirfenair is indicated in adults for the treatment of mild to moderate IPF.

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

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Pirfenidone Sandoz, Fredalix and Pirfenair, together with measures to minimize such risks and the proposed studies for learning more about Pirfenidone Sandoz, Fredalix and Pirfenair 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 healthcare professionals;
- 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 Sandoz, Fredalix and Pirfenair, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Sandoz, Fredalix and Pirfenair are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be taken safely. 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 Sandoz, Fredalix and Pirfenair. 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 5– Part VI: 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)
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

Important identified risk: Photosensitivity reaction and rash	
Risk minimization measures	<u>Routine risk communication:</u> SmPC Sections 4.2, 4.4 and 4.8. PL Section 2, 3 and 4. <u>Routine risk minimization activities recommending specific clinical measures to address the risk:</u> SmPC sections 4.2, 4.4 and PL section 2, 4: It has been advised to avoid or minimize the exposure to direct sunlight during treatment with Pirfenidone Sandoz, Fredalix and Pirfenair. Also, instructions are included to protect against sun exposure by wearing protecting cloth and avoiding use of medicines known to cause photosensitivity. Instructions to report symptoms of photosensitivity reaction or rash to their physician. <u>Other routine risk minimization measures beyond the Product Information:</u>

Important identified risk: Photosensitivity reaction and rash	
	Legal status: Prescription only medicine **Additional risk minimization measures:** Safety checklist for prescribing physician

Important identified risk: DILI	
Risk minimization measures	Routine risk communication: SmPC Sections 4.2, 4.3, 4.4 and 4.8. PL Section 2, 3 and 4. Routine risk minimization activities recommending specific clinical measures to address the risk: SmPC sections 4.2, 4.3, 4.4 and PL section 2, 3, 4: It has been advised to not use Pirfenidone Sandoz, Fredalix and Pirfenair in patient with severe hepatic impairment or end stage liver disease. Instruction to perform liver function test before and during the treatment with Pirfenidone Sandoz, Fredalix and Pirfenair. Advise to reduce Pirfenidone Sandoz, Fredalix and Pirfenair dose based on clinical symptoms. Other routine risk minimization measures beyond the Product Information: Legal status: Prescription only medicine **Additional risk minimization measures:** Safety checklist for prescribing physician

II.C Post-authorization development plan

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 Sandoz, Fredalix and Pirfenair.

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

There are no studies required for Pirfenidone Sandoz, Fredalix and Pirfenair.