Part VI: Summary of the risk management plan

Summary of risk management plan for Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter (Pirfenidone)

This is a summary of the risk management plan (RMP) for Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter. The RMP details important risks of Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter, how these risks can be minimised, and how more information will be obtained about Pirfenidon Medical Valley 267 mg,534 mg and 801 mg filmdragerade tabletter 's risks and uncertainties (missing information).

Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter should be used.

Important new concerns or changes to the current ones will be included in updates of Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter’s RMP.

I. The medicine and what it is used for

Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter is authorised in adults for the treatment of idiopathic pulmonary fibrosis (IPF).

It contains Pirfenidone as the active substance, and it is given by the oral route.

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

Important risks of Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter, together with measures to minimise such 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 Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter, 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 Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter 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 Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter. 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 • DILI
• Important potential risks	• None
Missing information	• None

DILI=drug-induced liver injury

II.B Summary of important risks

Important identified risk - Photosensitivity reaction and rash	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Routine risk communication:

Important identified risk - Photosensitivity reaction and rash	
	SmPC Section 4.2 (Posology and method of administration) SmPC Section 4.4 (Special warnings and precautions for use) SmPC Section 4.8 (Undesirable effects) PIL Section 2 (What you need to know before you take Pirfenidon Medical Valley – warnings and Precautions) PIL Section 3 (How to take Pirfenidon Medical Valley – Dose reduction due to side effects) PIL Section 4 (Possible side effects) <u>Additional risk minimization measures:</u> Physician information (safety checklists)
Important identified risk - DILI	
Risk minimisation measures	<u>Routine risk minimization measures:</u> Routine risk communication: 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) PIL Section 2 (What you need to know before you take Pirfenidon Medical Valley – warnings and Precautions) PIL Section 3 (How to take Pirfenidon Medical Valley – Dose reduction due to side effects) PIL Section 4 (Possible side effects) <u>Additional risk minimization 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 Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter.

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

There are no studies required for Pirfenidon Medical Valley 267 mg, 534 mg and 801 mg filmdragerade tabletter.