SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN

Fenifib® (PIRFENIDONE)

This checklist supports safe and effective use of pirfenidone and the management of important risks (Drug-induced Liver Injury (DILI), Photosensitivity). It should be read carefully before prescribing.

Before initiating Pirfenidone and in addition to reading the Summary of Product Characteristics (SmPC), please check each of the following:

Indication for use

- I am satisfied that the patient is an adult with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF).
- I have started therapy at 267 mg three times a day and the patient has been advised that therapy will be titrated according to the recommendations of the Summary of Product Characteristics (SmPC).
- I have advised the patient to take Pirfenidone with food and to avoid grapefruit and grapefruit juice while they are being treated with Pirfenidone.

Drug-induced Liver Injury

Prior to initiation of treatment:

- The patient does not have severe hepatic impairment or end stage liver disease. Pirfenidone is contraindicated in patients with severe hepatic impairment or end stage liver disease
- Liver function tests have been performed prior to initiation of treatment with Pirfenidone
- I am aware that elevations of serum transaminases can occur during treatment with Pirfenidone.
- The patient is informed that serious liver injury may occur and that he/she should contact their prescribing physician or regular physician immediately for clinical evaluation and liver function tests if symptoms of liver injury including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice (as described in the patient information leaflet) occur.

During treatment:

- Liver function tests will be performed monthly in the first six months of treatment.
- Liver function tests will be performed every three months thereafter during treatment.
- Patients who develop liver enzyme elevations will be closely monitored and the dose of Pirfenidone will be adjusted or treatment will be permanently discontinued if necessary (please refer to the SmPC for recommendations).
- Prompt clinical evaluation and liver function tests will be performed if a patient develops symptoms or signs of liver injury (please refer to the SmPC for recommendations).

Photosensitivity

- The patient is informed that Pirfenidone is known to be associated with photosensitivity reactions and that preventive measures have to be taken.
- The patient is advised to avoid or reduce exposure to direct sunlight (including sunlamps).
- The patient is instructed to use a sunblock daily, to wear clothing that protects against sun exposure,

and to avoid other medications known to cause photosensitivity.

- The patient is informed that he/she should report to the prescribing physician or regular physician if any new and significant skin rash occurs.

Reporting of adverse events

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. If you become aware of any suspected adverse drug reactions (ADR) associated with the use of Pirfenidone, including clinically significant photosensitivity reactions and skin rashes, drug induced liver injury, clinically significant abnormal liver function tests and any other clinically significant ADRs, please report such information.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse event reporting

Please report suspected adverse drug reactions (ADRs) to The National Pharmacovigilance Centre (NPC-Saudi Food and Drug Authority (SFDA)).

SFDA Call Centre: 19999
E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa/

For further copies of this guide please contact Al-Hobail Pharmaceutical for Medical information, please contact:

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