

Pirfenidone 267mg/801mg Fenido | Safety Checklist for Prescribing Physician

This safety checklist contains key elements to follow when prescribing Pirfenidone.

Liver Function:

- Pirfenidone is contraindicated in patients with severe hepatic impairment or end stage liver disease.
- Elevations of serum transaminases can occur during treatment with Pirfenidone.
- There is a need to monitor liver function tests prior to initiation of treatment with Pirfenidone and at regular intervals thereafter.
- Close monitoring is required of any patients who develop liver enzyme elevation. Appropriate dose adjustment or discontinuation may be required.

Photosensitivity:

- Patients should be informed that Pirfenidone is known to be associated with photosensitivity reactions and that preventative measures have to be taken.
- Patients are advised to avoid or reduce exposure to direct sunlight (including sunlamps).
- Patients should be instructed to use a sunblock daily, to wear clothing that protects against sun exposure, and to avoid other medications known to cause photosensitivity.

Before initiating Pirfenidone, in addition to reading the Summary of Product Characteristics (SmPC), please check the following points.

Indication for Use:

- ☐ The patient is an adult with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF).
- ☐ 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 SmPC.
- ☐ Advised the patient to take Pirfenidone with food and to avoid grapefruit juice while they are being treated with Pirfenidone.

Key warnings: please check

Before Starting Pirfenidone I have:

- ☐ Checked whether the patient is hypersensitive to Pirfenidone.
- ☐ Checked whether the patient is on medication which could potentially interact adversely with Pirfenidone.
- ☐ Checked whether the patient has underlying hepatic disease.
- ☐ Arranged for adequate monitoring for abnormal liver function tests.
- ☐ Advised the patient to avoid the sun and all sources of U.V. light, to wear clothing that protects against sun exposure and advised patients of what other measures can be taken such as taking extra care during the summer months.

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.

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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.

I understand that I will report all adverse reactions in accordance with the national reporting requirements to the address below.

I understand that it is particularly important I report serious adverse reactions and clinically significant adverse drug reactions (ADR) of special interest including:

- ☐ Photosensitivity reactions and skin rashes
- ☐ Abnormal liver function tests
- ☐ Any other clinically significant ADRs based on my judgment

I will refer to the Summary of Product Characteristics for further information on use of Pirfenidone

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.

Adverse events should be reported. Report any suspected adverse reactions to the competent authority in Saudi Arabia as per details below:

The National Pharmacovigilance Centre (NPC)

SFDA Call Centre: 19999 | E-mail: npc.drug@sfd.gov.sa
Website: <https://ade.sfd.gov.sa/>

Marketing Authorization Holder: Boston Oncology Arabia

Phone: +966 54 764 3672 | E-mail: pv@bostononcology.com

To report the adverse event in other GCC States - Please contact the relevant competent authority.