# SAFETY CHECKLIST FOR PRESCRIBING PHYSICIAN

## Donfer (Pirfenidone Tablets 267 mg & 801 mg)

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA)

**This Safety Checklist Contains Key Elements to Follow When Prescribing Pirfenidone Tablets**

This document is to ensure the safe, effective, and responsible prescribing of medications by providing a systematic approach to identifying potential risks, minimizing errors, and optimizing patient outcomes through adherence to evidence-based practices, legal requirements, and patient-centered care principles.

**It is advised to be read carefully before prescribing/dispensing/administering the product.**

**Associated Risks**

- **Liver function, drug induced liver injury**

1. Pirfenidone is contraindicated in patients with severe hepatic impairment or end stage liver disease.
2. Elevations of serum transaminases can occur during treatment with Pirfenidone.
3. There is a need to monitor liver function tests prior to initiation of treatment with Pirfenidone and at regular intervals thereafter.
4. Close monitoring is requited of any patients who develop liver enzyme elevation with appropriate dose adjustment or discontinue.
5. Prompt clinical evaluation and liver function tests for patients who develop signs or symptoms of liver injury.

- **Photosensitivity**

1. Patients should be informed that Pirfenidone is associated with photosensitivity reactions and that preventive measures have to be taken.
2. Patients are advised to avoid or reduce exposure to direct sunlight (including sunlamps).
3. 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, 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 |
| **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 |
| ☐ | Arranged for adequate monitoring for abnormal liver function tests |

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**Drug-induced Liver Injury**

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|---|---|
| **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 Pirfenidon |
| ☐ | 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 |

**Once pirfenidone has been administered, I have asked the patient to contact me or their regular physician if they experience:**

| | |
|---|---|
| ☐ | Any new and significant skin rash |
| ☐ | If the skin or the whites of the eyes turn yellow of if they experience dark urine |
| ☐ | Any worrying or alarming symptoms or signs which might be related to pirfenidone |

**Please refer to the summary of product characteristics for further information on safe use.**

| **Reporting of adverse events:** |
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| 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 are aware of any suspected adverse reactions associated with the use of pirfenidone, please report it to:

| Saudi Food and Drug Authority (SFDA) | Pharma Pharmaceutical Industries & biological products (PPI) |
|---|---|
| **SFDA Call Center:** 19999<br>**E-mail:** npc.drug@sfda.gov.sa<br>**Website:** http://ade.sfda.gov.sa/<br><br>Please visit the below barcode to report | **E-mail:** Abdulrahman@pharma.com.sa<br>**Mobile:** +966 580303838<br>**Website:** https://pharma.com.sa/inquiry/<br><br>Please visit the below barcode to report |