

## **Fenifib<sup>®</sup> (PIRFENIDONE)**

### **“Important Information to Minimize the Risks Associated with the Use of Fenifib<sup>®</sup> (PIRFENIDONE )**

This booklet is designed to support adult patients who have been prescribed Fenifib<sup>®</sup> (PIRFENIDONE ) for the treatment of idiopathic pulmonary fibrosis (IPF), a condition that predominantly affects older adults (over 60 years) and is more common in men than in women.  
(The primary goal in managing IPF is to slow down the decline in lung function.)

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## Treatment with Pirfenidone

For more information about Pirfenidone, please read the patient information leaflet approved with the medicine

## What is Pirfenidone and how is it used?

- It contains the active ingredient (Pirfenidone), which works to slow the formation of scarring and fibrosis in the lungs.
- Pirfenidone is used to treat mild to moderate idiopathic pulmonary fibrosis (IPF) in adults

## How long does it take for Pirfenidone to work ?

Since lung scarring develops gradually, treatment with Pirfenidone usually takes 3 to 6 months to start working. It is important to understand that you may not feel any difference during treatment, and it may not be effective for every patient.

## How to Take Pirfenidone

**Pirfenidone should always be taken as directed by your doctor**

**Upon initiating treatment, the dose should be titrated to the recommended daily dose of 2403 mg/day over a 14-day period as follows:**

**Days 1 to 7: a dose of 267 mg administered three times a day (801 mg/day)**

**Days 8 to 14: a dose of 534 mg administered three times a day (1602 mg/day)**

**Day 15 onward: a dose of 801 mg administered three times a day (2403 mg/day)**

**Patients who miss 14 consecutive days or more of Pirfenidone Tablets treatment should re-initiate therapy by undergoing the initial 2-week titration regimen up to the recommended daily dose.**

**For treatment interruption of less than 14 consecutive days, the dose can be resumed at the previous recommended daily dose without titration.**

**Pirfenidone should always be taken with food and water during or after a meal, as this helps reduce the chances of side effects.**

**Do not take more than 2403 mg of Pirfenidone per day.**

**It is important to continue taking the full dose as directed by your doctor.**

**The tablet should be swallowed whole (do not chew it)**

## Take Pirfenidone three times a day with food

<b>From Day 1 to Day 7</b>	<b>One tablet (267 mg), three times a day</b>
<b>From Day 8 to Day 14</b>	<b>Two tablets (267 mg), three times a day</b>
<b>Day 15 and onwards</b>	<b>Either one tablet (801 mg) three times a day, or three tablets (267 mg) three times a day</b>

## If you forget to take a dose, follow these instructions

- If more than three hours remain before your next dose, take the missed dose immediately with food.
- If less than three hours remain before your next dose, wait and take the next dose at the usual time.
- Do not take two doses at the same time to make up for a missed dose.

## Take Pirfenidone with food to avoid side effects

<b>Gastrointestinal problems</b>	Nausea, tiredness, diarrhea, and indigestion
<b>Sun sensitivity and rash</b>	a high-protection sunscreen (SPF 50+) and cover your skin to reduce the risk of rash
<b>Fatigue</b>	If you feel very tired, tell your doctor. They may suggest lowering your dose for a while and then going back to the full dose later.
<b>Liver function</b>	You will need a blood test before starting Pirfenidone and for the first 6 months after starting
<b>Weight loss</b>	It may cause weight loss. Your doctor will monitor your weight during treatment with this medicine

## What to do next

Your doctor will regularly monitor your health, and you will have tests, which include :

### Lung function tests

measure how much air you can exhale in one breath compared to the amount of air you can inhale, and another test checks how well your lungs can absorb oxygen

### Stress test

The 6-minute walk test checks how far you can walk in 6 minutes and helps monitor your condition

### Lung examination (listening with a stethoscope)

The doctor examines your lungs with a stethoscope to see if there are any changes compared to .previous tests

### Lung scan (CT scan)

The lungs are examined using a machine that takes detailed images to see if there are any changes .compared to previous tests

## Liver test

Routine blood tests to check how well the liver is working

Period	Follow-up / Tests
Before starting treatment	<ul style="list-style-type: none"><li>• Liver function test</li></ul>
From Month 1 to Month 6	<ul style="list-style-type: none"><li>• Liver function test monthly (every 4 weeks)</li><li>• Follow-up visit to check how well you are tolerating the medicine and responding to treatment</li></ul>
After Month 6	<ul style="list-style-type: none"><li>• Liver test every 3 months</li><li>• Regular check-ups based on how stable your condition is</li></ul>

## Recording personal weight

### Living with Idiopathic Pulmonary Fibrosis (IPF) and Its Treatment

- Living with a chronic illness and staying positive at the same time can be challenging. Your doctor will guide you on how to manage your daily life.
- You may also find additional support by following a healthy diet, exercising, and making lifestyle changes, such as quitting

[illegible]

### **Adverse event reporting**

Please report suspected adverse drug reactions (ADRs) to The National Pharmacovigilance Centre (NPC).

SFDA Call Centre: 19999

E-mail: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa) Website: <https://ade.sfd.gov.sa/>



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