

Patient Guide
Information for Patients
(Important Risk Minimization)
Donfer (Pirfenidone Tablets 267 mg & 801 mg)

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

This guide will make you aware of the following:

- ✓ What this medicine is
- ✓ Who it is for
- ✓ How to take it
- ✓ What side effects to watch for

What is Pirfenidone?

Pirfenidone is an anti-fibrotic medicine. Anti-fibrotic medicines are designed to slow down the development of scarring (fibrosis) in the lungs. Pirfenidone is used to treat a lung disease called idiopathic pulmonary fibrosis (IPF). This disease causes the lungs to get scarred and become stiff, making it hard to breathe. It may also have a role in treating Progressive Fibrosing Interstitial Lung Disease (PF-ILD) which is a group of lung diseases that causes scarring in the lungs.

Why have I been prescribed Pirfenidone?

You have been prescribed Pirfenidone because you have a condition called idiopathic pulmonary fibrosis (IPF). IPF is a serious lung condition in which the lungs become scarred, and breathing becomes increasingly difficult. 'Idiopathic' means that the cause is unknown. As scar tissue (known as 'fibrosis') increases in the lungs, the lungs become smaller and stiffer. This leads to coughing and increasing breathlessness. IPF is a progressive disease, which means that it will get worse over time, but the rate at which it progresses varies from person to person. If it is not treated, it may be life-limiting. Pirfenidone won't cure your lung condition or reverse any existing scarring, but it can effectively slow down the rate of your lung function decline.

Is pirfenidone right for me?

Your doctor recommends this medicine for your treatment. But some patients should not take pirfenidone. Tell your doctor:

- If you are allergic to pirfenidone or any other medicines.
- If you have ever had serious liver disease or kidney disease.
- If you are on dialysis. Patients on dialysis should not use pirfenidone.
- For women:
 - If you are pregnant or trying to become pregnant.
 - Do not breastfeed while taking this medicine.

What do I need to know when taking this medicine?

Pirfenidone can interact with other medicines and health products. This means it might not work well with these products.

Tell your doctor:

- About all the medicines, supplements and herbal products you are taking. Tell your pharmacist too.
- If you are taking Ciprofloxacin or fluvoxamine, avoid these medicines while you are taking pirfenidone.
- If you plan to become pregnant. Use birth control to be sure you or your partner will not become pregnant while you are taking this medicine.

What should I avoid while taking it?

- Avoid smoking while taking this medicine. Smoking may lower the medicine's effect on your lungs.
- Avoid grapefruit and grapefruit juice while taking this medicine

How to take this medicine?

- Treatment with Donfer should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of IPF.
- 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).
- The recommended maintenance daily dose of Donfer is 801 mg three times a day with food for a total of 2403 mg/day.
- Doses above 2403 mg/day are not recommended for any patient.
- Patients who miss 14 consecutive days or more of Donfer 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.

What are the side effects of this medicine?

Pirfenidone may cause side effects. Serious side effects are not common but can happen if you are taking this medicine.

Tell your doctor if you have any of these symptoms:

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| ➤ Upset stomach | ➤ Photosensitivity |
| ➤ Nausea, vomiting, or both | ➤ Lack of energy |
| ➤ Diarrhoea (watery bowel movement) | ➤ Loss of appetite |
| ➤ Weight loss | ➤ Dizziness |
| ➤ Yellowish skin colour | ➤ Heartburn |

How can I reduce any side effects?

Take pirfenidone with food. This will help to avoid having an upset stomach, nausea, vomiting, heart burn or diarrhoea.

Pirfenidone can make you feel dizzy.

- Take Pirfenidone with food to lower the chance of becoming dizzy.
- Avoid driving or operating heavy machinery after your first few doses of this medicine. See how you react.
- If you feel dizzy, speak to your doctor. See if your doctor can lower your dose to reduce side effects.

Pirfenidone can cause sun sensitivity and skin rash.

- Stay out of the sun while taking this medicine.
- If you must be out in the sun, protect your skin. Wear long sleeves, a wide-brimmed hat and sunblock (at least SPF 50).

What follow-up care will I need?

Your doctor will order lab tests to see how well pirfenidone is working. These tests can also help your doctor check for any side effects. While you take this medicine, you will have regular tests to check:

- Your blood counts (white blood cells, red blood cells, platelets)
- Your liver enzymes

Who can I call if I have questions or concerns?

Please talk to the doctor or pharmacist. They can answer any questions or concerns about pirfenidone.

To Report Side Effects:

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