

Patient Information
Pirfenidone Tablets
 (pir FEN i done)

What are pirfenidone tablets?

- Pirfenidone tablets are a prescription medicine used to treat people with a lung disease called idiopathic pulmonary fibrosis (IPF).
- It is not known if pirfenidone tablets are safe and effective in children.

Before you take pirfenidone tablets, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have kidney problems
- are a smoker
- are pregnant or plan to become pregnant. It is not known if pirfenidone tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if pirfenidone passes into your breast milk. You and your doctor should decide if you will take pirfenidone tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take pirfenidone tablets?

- Take pirfenidone tablets exactly as your doctor tells you to take it.
- Your doctor may change your dose of pirfenidone tablets as needed.
- Take pirfenidone tablets with food at the same time each day. This may help to decrease your nausea and dizziness.
- **Pirfenidone 267 mg is supplied as a yellow tablet. If you have been prescribed pirfenidone 267 mg, take it as follows:**
 - Take pirfenidone 267 mg tablet 3 times each day for days 1 through 7.
 - Take pirfenidone 267 mg tablet 3 times each day for days 8 through 14.
 - Take pirfenidone 267 mg tablet 3 times each day on day 15 and each day after.

Pirfenidone Tablets 267 mg Dosing Schedule				
Week	Morning (Breakfast)	Afternoon (Lunch)	Evening (Dinner)	Total Pills Each Day
Days 1 to 7	1	1	1	3
Days 8 to 14	2	2	2	6
Days 15 onward	3	3	3	9

- **If you have been prescribed the brown 801 mg pirfenidone tablets, take it as follows:**
 - Take 1 brown 801 mg pirfenidone tablet 3 times each day.

Pirfenidone Tablets 801 mg Dosing Schedule				
Week	Morning (Breakfast)	Afternoon (Lunch)	Evening (Dinner)	Total Pills Each Day
Days 15 onward	1	1	1	3

- If you miss 14 days or more of pirfenidone tablets call your doctor right away for further instructions about how to take your medicine.
- **Do not** take 2 doses at the same time to make up for your missed dose.

- **Do not** take more than 3 doses each day.
- If you take too much pirlfenidone tablets, call your doctor or go to the nearest hospital emergency room right away.
- Your doctor should do certain blood tests before you start taking pirlfenidone tablets.

What should I avoid while taking pirlfenidone tablets?

- Avoid sunlight. Pirlfenidone tablets can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You could get a severe sunburn. Use sunscreen (SPF 50) and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your doctor if you get sunburn or a rash.
- Avoid taking pirlfenidone tablets with other medicines that can make your skin sensitive to the sun, the light from sunlamps and tanning beds.
- Avoid smoking. Smoking may affect how well pirlfenidone tablets works.

What are the possible side effects of pirlfenidone tablets?

Pirlfenidone tablets may cause serious side effects, including:

- **liver problems.** Call your doctor right away if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea colored) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal, feeling tired.

Your doctor will do blood tests to check how your liver is working during your treatment with pirlfenidone tablets.

- **sensitivity to sunlight (photosensitivity) and rash.** See “What should I avoid while taking pirlfenidone tablets?”

- **stomach problems.** Pirlfenidone tablets may cause stomach problems such as nausea, vomiting, diarrhea, indigestion, heartburn, and stomach pain. Tell your doctor right away if your stomach problems get worse or do not go away. Your doctor may need to change your dose of pirlfenidone tablets.

The most common side effects of pirlfenidone tablets include feeling tired, insomnia, upper respiratory tract infections, sinusitis, headache, dizziness, decreased weight and decreased or loss of appetite.

These are not all the possible side effects of pirlfenidone tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store pirlfenidone tablets?

- Store pirlfenidone tablets at room temperature, 77°F (25°C).
- Carton containing 3 bottles, each containing ninety 267 mg tablets (270 tablets total) comes in a child-resistant package.
- Bottle containing ninety 801 mg tablets comes in a child-resistant package.
- Keep in a tightly closed container.

Safely throw away any pirlfenidone tablets that is out of date or no longer needed. **Keep pirlfenidone tablets and all medicines out of reach of children.**

General information about the safe and effective use of pirlfenidone tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use pirlfenidone tablets for a condition for which it was not prescribed. Do not give pirlfenidone tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for

information about pirfenidone tablets that is written for health professionals.

What are the ingredients in pirfenidone tablets?

Active ingredient: pirfenidone

Inactive ingredients: copovidone, croscarmellose sodium, lactose monohydrate, macrogol (polyethylene glycol), magnesium stearate, polyvinyl alcohol, iron oxide yellow (267 mg), iron oxide black (801 mg), iron oxide red (801 mg), talc and titanium dioxide. For more information, go to www.accordhealthcare.us or call Accord Healthcare Inc. at 1-866-941-7875.

This Patient Information has been approved by the U.S. Food and Drug Administration

Manufactured For:

Accord Healthcare, Inc.,
1009 Slater Road,
Suite 210-B,
Durham, NC 27703,
USA

Manufactured By:

Intas Pharmaceuticals Limited,
Plot No. 5 to 14, Parmez,
Near Village Matoda, Sarkhej-Bavla Highway,
No. 8-A, Taluka Sanand, Ahmedabad,
Gujarat 382213, India.

51 3059 1 730724

Issued August 2022