

Patient Information
Pirfenidone Tablets, USP
(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 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 film-coated tablet 267 mg is supplied as a yellow tablet. If you have been prescribed pirfenidone tablets 267 mg, take it as follows:**
 - Take 1 pirfenidone 267 mg tablet 3 times each day for days 1 through 7.
 - Take 2 pirfenidone 267 mg tablets 3 times each day for days 8 through 14.
 - Take 3 pirfenidone 267 mg tablets 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 1-7	1	1	1	3
Days 8-14	2	2	2	6
Days 15 onward	3	3	3	9

- **If you have been prescribed the brown 801 mg pirfenidone film-coated 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 pirfenidone 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 pirfenidone tablets.

What should I avoid while taking pirfenidone tablets?

- Avoid sunlight. Pirfenidone 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 pirfenidone 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 pirfenidone tablets works.

What are the possible side effects of pirfenidone tablets?

Pirfenidone 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 pirfenidone tablets.
- **sensitivity to sunlight (photosensitivity) and rash.** See “**What should I avoid while taking pirfenidone tablets?**”
- **severe skin reactions.** Call your doctor right away if you have a severe skin reaction such as skin blisters, rash, sores in the mouth, hives or any other severe skin symptoms. Your doctor may stop your treatment with pirfenidone tablets.
- **stomach problems.** Pirfenidone 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 pirfenidone tablets.

The most common side effects of pirfenidone 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 pirfenidone 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 pirfenidone tablets?

- Store pirfenidone tablets at room temperature, 66°F to 77°F (20°C to 25°C).
- Keep in a tightly closed container.

Safely throw away any pirfenidone tablets that is out of date or no longer needed.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

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use pirfenidone tablets for a condition for which it was not prescribed. Do not give pirfenidone 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: colloidal silicon dioxide, ferric ferrous oxide (801 mg only), ferric oxide red (801 mg only), ferric oxide yellow (267 mg only), hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, talc and titanium dioxide.

For more information, go to www.apotex.com or call 1-800-706-5575.

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

APOTEX INC
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267 mg and 801 mg

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Apotex Inc.
Toronto, Ontario
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