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[Home](#) → [Drugs, Herbs and Supplements](#) → Pirfenidone

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Pirfenidone

pronounced as (pir fen' i done)

Why is this medication prescribed?

Pirfenidone is used for the treatment of idiopathic pulmonary fibrosis (scarring of the lungs with an unknown cause). Pirfenidone is in a class of medications called pyridones. It is not known exactly how pirfenidone works to treat idiopathic pulmonary fibrosis.

How should this medicine be used?

Pirfenidone comes as a capsule to take by mouth. It is usually taken with food three times a day. Take pirfenidone capsules at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take pirfenidone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Your doctor will start you on a low dose of pirfenidone and gradually increase your dose over a 2-week period.

Your doctor may need to decrease your dose or stop treatment if you experience certain severe side effects. Be sure to tell your doctor how you are feeling during your treatment.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking pirfenidone,

- tell your doctor and pharmacist if you are allergic to pirfenidone, any other medications, or any of the ingredients in pirfenidone capsules. Ask your pharmacist or check the manufacturer's patient information for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Teril); cimetidine (Tagamet); ciprofloxacin (Cipro); digoxin (Lanoxin); enoxacin (Penetrex); fluvoxamine (Luvox); or rifampin

(Rifadin, Rimactane, in Rifamate, in Rifater). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you have or have ever had liver or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking pirfenidone, call your doctor.
- tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this medication. You should stop smoking before you start taking pirfenidone and avoid smoking during your treatment.
- plan to avoid unnecessary or prolonged exposure to sunlight (including sunlamps and tanning beds) and to wear protective clothing, sunglasses, and sunscreen (SPF 50 or higher). Pirfenidone may make your skin sensitive to sunlight. Ask your doctor or pharmacist about avoiding other medications that may make your skin sensitive to sunlight. If your skin becomes reddened, swollen, or blistered, like a bad sunburn, call your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

If you miss 14 or more days of pirfenidone treatment, call your doctor. Your doctor will tell you how to restart at a low dose and then increase your dose gradually over 2 weeks.

What side effects can this medication cause?

Pirfenidone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- heartburn
- stomach pain
- headache
- dizziness
- pressure or tenderness in the sinuses
- difficulty falling asleep or staying asleep
- joint pain
- weight loss

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- rash
- extreme tiredness
- unusual bleeding or bruising
- lack of energy
- loss of appetite
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- dark or brown (tea-colored) urine
- flu-like symptoms
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing

Pirfenidone may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Do not use the medication if the seal over the opening of the bottle from the manufacturer is broken or missing when you first receive it.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to pirfenidone.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Esbriet®

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