

Patient Information
ESBRIET (es-BREE-et)
(pirfenidone)
capsules and film-coated tablets

What is ESBRIET?

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

Before you take ESBRIET, 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 ESBRIET will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ESBRIET passes into your breast milk. You and your doctor should decide if you will take ESBRIET.

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

How should I take ESBRIET?

- Take ESBRIET exactly as your doctor tells you to take it.
- Your doctor may change your dose of ESBRIET as needed.
- Take ESBRIET with food at the same time each day. This may help to decrease your nausea and dizziness.
 - **ESBRIET 267 mg is supplied as either a white to off-white capsule or a yellow tablet. If you have been prescribed ESBRIET 267 mg, take it as follows:**
 - Take 1 ESBRIET 267 mg capsule or tablet 3 times each day for days 1 through 7.
 - Take 2 ESBRIET 267 mg capsule or tablet 3 times each day for days 8 through 14.
 - Take 3 ESBRIET 267 mg capsule or tablet 3 times each day on day 15 and each day after.

Esbriet 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 ESBRIET film-coated tablets, take it as follows:**
 - Take 1 brown 801 mg ESBRIET tablet 3 times each day.

Esbriet 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 ESBRIET 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 ESBRIET, call your doctor or go to the nearest hospital emergency room right away.
- Your doctor should do certain blood tests before you start taking ESBRIET.

What should I avoid while taking ESBRIET?

- Avoid sunlight. ESBRIET 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 ESBRIET 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 ESBRIET works.

What are the possible side effects of ESBRIET?**ESBRIET 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 ESBRIET.
- **sensitivity to sunlight (photosensitivity) and rash.** See “What should I avoid while taking ESBRIET?”
- **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 ESBRIET.
- **stomach problems.** ESBRIET 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 ESBRIET.

The most common side effects of ESBRIET 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 ESBRIET. 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 ESBRIET?

- Store ESBRIET capsules and tablets at room temperature, 77°F (25°C).
- Keep in a tightly closed container.

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

General information about the safe and effective use of ESBRIET.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ESBRIET for a condition for which it was not prescribed. Do not give ESBRIET 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 ESBRIET that is written for health professionals.

What are the ingredients in ESBRIET capsules?

Active ingredient: pirfenidone

Inactive ingredients: microcrystalline cellulose, croscarmellose sodium, povidone, and magnesium stearate

Capsule Shell: gelatin and titanium dioxide

Capsule Brown Printing Ink: shellac, iron oxide black, iron oxide red, iron oxide yellow, propylene glycol, ammonium hydroxide

What are the ingredients in ESBRIET film-coated tablets?

Active ingredient: pirfenidone

Inactive ingredients: microcrystalline cellulose, colloidal anhydrous silica, povidone, croscarmellose sodium, magnesium stearate, polyvinyl alcohol, titanium dioxide, macrogol (polyethylene glycol), talc, and iron oxide

For more information, go to www.ESBRIET.com or call 1-888-835-2555.

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