

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

^{Pr}ESBRIET®

pirfenidone

Hard capsules (267 mg)

Film coated tablets (267 mg and 801 mg)

Anti-fibrotic/Anti-inflammatory Agent

Hoffmann-La Roche Limited
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Mississauga, Ontario, Canada
L5N 5M8

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**ESBRIET**[®]

pirfenidone hard capsules and film coated tablets

Read this carefully before you start taking **ESBRIET** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ESBRIET**.

Serious Warnings and Precautions

- **Severe Drug Interactions** can occur if **ESBRIET** is taken in combination with some other medications. In particular, do not take **ESBRIET** with **fluvoxamine**.
- Talk to your doctor if you are currently taking **ciprofloxacin** (antibiotic). A dose adjustment may be required.
- If you currently take fluvoxamine, a different medication should be prescribed for you before you begin taking **ESBRIET**.

What is **ESBRIET** used for?

- **ESBRIET** is used for the treatment of idiopathic pulmonary fibrosis (IPF) in adults.

How does **ESBRIET** work?

How **ESBRIET** works is not yet fully understood. It may reduce inflammation and fibrosis in your lungs. It may slow down worsening of your IPF.

What are the ingredients in **ESBRIET**?

Medicinal ingredients: pirfenidone

Non-medicinal ingredients:

Capsules: Ammonium hydroxide, black iron oxide, croscarmellose sodium, gelatin, magnesium stearate, microcrystalline cellulose, povidone, propylene glycol, red iron oxide, shellac, titanium dioxide, yellow iron oxide

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

ESBRIET comes in the following dosage forms:

267 mg hard capsules

267 mg (yellow), 801 mg (brown) film-coated tablets

Do not use **ESBRIET** if:

- If you are allergic to pirfenidone or any of the other ingredients in this medicine.
- If you have previously experienced angioedema with pirfenidone, including symptoms such as swelling of the face, lips and/or tongue which may be associated with difficulty breathing or wheezing.

- If you have severe or end-stage liver disease.
- If you have severe or end-stage kidney disease or you require dialysis.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ESBRIET. Talk about any health conditions or problems you may have, including if you:

- Have liver or kidney problems or disease.
- Are pregnant or planning to become pregnant. It is not known whether taking ESBRIET may be harmful to an unborn baby.
- Are breastfeeding or planning to do so. It is not known if ESBRIET passes into breast milk.

Other warnings you should know about:

Driving and using machines: Before you perform tasks which may require you to be alert and coordinated, wait until you know how you will respond to ESBRIET. Dizziness and tiredness can occur when you take ESBRIET. Taking ESBRIET with food may decrease dizziness. Be careful when driving or using machines.

Increased sensitivity to sunlight: You may become more sensitive to sunlight when taking ESBRIET.

You should:

- Avoid (not take) other medicines which may make you more sensitive to sunlight. Ask your pharmacist if you are not sure.
- Avoid or minimize exposure to direct or indirect sunlight, including through windows and from sunlamps.
- Wear an effective sunblock daily (at least SPF 50, against UVA and UVB).
- Wear clothing that protects against sun exposure such as a wide-brimmed hat and long sleeves.
- Seek shade.

ESBRIET can cause weight loss. Your doctor will monitor your weight while you are taking this medicine.

Do not drink grapefruit juice during the time that you are taking ESBRIET. Grapefruit juice may prevent ESBRIET from working properly.

Do not smoke before and during treatment with ESBRIET. Cigarette smoking may reduce the effect of ESBRIET.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ESBRIET:

Serious Drug Interactions
<ul style="list-style-type: none"> • Severe Drug Interactions can occur if ESBRIET is taken in combination with some other medications. In particular, do not take ESBRIET with fluvoxamine. • Talk to your doctor if you are currently taking ciprofloxacin (antibiotic). A dose adjustment may be required. • If you currently take fluvoxamine, a different medication should be prescribed for you before you begin taking ESBRIET.

- Amiodarone, mexiletine or quinidine to treat abnormal heart rhythm
- Bupropion, duloxetine, fluoxetine, moclobemide, or paroxetine to treat depression and/or anxiety
- Carbamazepine or phenytoin to treat seizure
- Cinacalcet to treat parathyroid condition
- Ciprofloxacin to treat bacterial infection
- Esomeprazole or omeprazole to treat heartburn
- Fluconazole, miconazole, terbinafine, or voriconazole to treat fungal infections
- Methoxsalen to treat skin conditions such as psoriasis
- Oral contraceptives (the Pill for birth control)
- Rifampin, a type of antibiotic, to treat bacterial infection

How to take ESBRIET:

ESBRIET should only be prescribed and monitored by physicians with the appropriate training and experience in the diagnosis and treatment of IPF.

Always take ESBRIET exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the capsules/tablets:

- Whole
- With a drink of water
- With food or during or after a meal to reduce the risk of side effects such as persistent stomach problems and dizziness (see **Serious side effects and what to do about them**)

Usual dose:

ESBRIET is usually prescribed in increasing doses as follows:

If taking capsules:

- **Days 1 to 7:** Take 1 capsule three times a day with food (a total of 3 capsules a day or 801 mg a day)
- **Days 8 to 14:** Take 2 capsules three times a day with food (a total of 6 capsules a day or 1602 mg a day)
- **Day 15 and onwards:** Take 3 capsules three times a day with food (a total of 9 capsules a day or 2403 mg a day)

If taking tablets:

- 267 mg tablets are **yellow** in colour.
- 801 mg tablets are **brown** in colour.
- **Days 1 to 7:** Take 1 **yellow** tablet three times a day with food (a total of 3 tablets a day or 801 mg a day)
- **Days 8 to 14:** Take 2 **yellow** tablets three times a day with food (a total of 6 tablets a day or 1602 mg a day)
- **Day 15 and onwards:** Take 3 **yellow** tablets three times a day with food **OR** take 1 **brown** tablet three times a day with food (a total of 2403 mg a day).

Your doctor may reduce your dose if you have:

- skin reactions to sunlight or sun lamps.
- significant changes to your liver enzymes.
- stomach problems.

If your stomach problems do not get better, your doctor may stop treatment with ESBRIET.

If you have not taken ESBRIET for 14 days or more in a row:

- your doctor will restart your treatment with the lowest dose.
- the dose will be gradually increased over 2 weeks to the usual dose.

Overdose:

If you think you, or a person you are caring for, have taken too much ESBRIET, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose is missed, the next dose should be taken as originally planned. Double doses should not be taken to make up for forgotten doses.

What are possible side effects from using ESBRIET?

These are not all the possible side effects you may have when taking ESBRIET. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Skin problems such as rash, itchy skin, skin redness, dry skin
- Tiredness, feeling weak or feeling low in energy
- Indigestion, heartburn, acid reflux, decreased appetite, changes in taste, bloating, abdominal pain and discomfort
- Infections of the throat or the airways going into the lungs and/or sinusitis, influenza and/or common cold
- Difficulty sleeping, feeling sleepy
- Headache
- Muscle pain, aching joints/joint pains
- Weight loss

ESBRIET may cause liver problems and other abnormal blood test results. You will need blood tests to check your blood levels and to make sure that your liver is working properly. Blood tests should be done before you start taking ESBRIET, at monthly intervals for the first 6 months and then every three months while you are taking this medicine. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Increased Sensitivity to Sunlight: skin reaction/rash to sunlight, blistering and/or marked peeling of the skin	✓		
Diarrhea	✓		
Fatigue	✓		
Persistent Stomach Problems: such as nausea, vomiting	✓		
COMMON			
Dizziness		✓	
UNCOMMON			
Liver Problems (abnormal blood test results related to your liver): yellow skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite			✓
Angioedema: swelling of the face, lips and/or tongue, difficulty breathing or wheezing			✓
RARE			
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Chest pain (angina), slow, fast or irregular heart beats			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store capsules/ tablets at room temperature (15 - 30°C).

Keep out of reach and sight of children.

If you want more information about ESBRIET:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.rochecanada.com, or by calling 1-888-762-4388.

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