

PRODUCT MONOGRAPH

Pr **ESBRIET**[®]

pirfenidone

Hard capsules (267 mg)

Film coated tablets (267 mg, and 801 mg)

Anti-fibrotic/Anti-inflammatory Agent

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario, Canada
L5N 5M8

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PART III: CONSUMER INFORMATION**PrESBRIET®**

pirfenidone hard capsules and film coated tablets

This leaflet is part III of a three-part "Product Monograph" published when ESBRIET® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ESBRIET®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

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

What it does:

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.

When it should not be used:

- 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.
- If you are taking:
 - fluvoxamine to treat depression and obsessive compulsive disorder (OCD)
 Tell your doctor or pharmacist if you are taking fluvoxamine. A different medication should be prescribed for you before you begin taking ESBRIET.

What the medicinal ingredient is:

Pirfenidone

What the non-medicinal ingredients are:

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.

What dosage form it comes in:

267 mg hard capsules

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

What ESBriet looks like and contents of the pack:**Capsules**

ESBRIET hard capsules (capsules) have a white to off-white opaque body and a white to off-white opaque cap with 'PFD 267 mg' printed in brown ink. The capsules contain a white to pale yellow powder.

Your medicine is provided in either a 2-week treatment initiation pack or in a bottle.

The 2-week treatment initiation pack contains a total of 63 capsules. There are 7 blister strips with 3 capsules per strip (1 capsule per pocket for Week 1) and 7 blister strips with 6 capsules per strip (2 capsules per pocket for Week 2).

The blister strips are each marked with the following symbols:



The bottle pack contains 270 capsules.

Tablets

ESBRIET film-coated tablets are oval, biconvex, debossed with "PFD."

- 267 mg tablets are **yellow** in colour. It comes in bottles of 21, 42, or 270 tablets.
- 801 mg tablets are **brown** in colour. It comes in bottles of 90 tablets.

WARNINGS AND PRECAUTIONS**BEFORE you use ESBRIET talk to your doctor or pharmacist if you:**

- Are taking fluvoxamine. Do not take ESBRIET with fluvoxamine.
- Are taking ciprofloxacin. A dose adjustment may be required if you take ciprofloxacin with ESBRIET.
- Are taking any other medications, obtained with or without a prescription, drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.
- Are normally exposed to direct or indirect sunlight.
- 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.

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.

INTERACTIONS WITH THIS MEDICATION

Severe Drug Interactions can occur if ESBRIET is taken in combination with some other medications. In particular, do not take ESBRIET with **fluvoxamine**.

If you currently take fluvoxamine, a different medication should be prescribed for you before you begin taking ESBRIET.

Be sure to tell your doctor or pharmacist about **all** the medicines you take (including medicines obtained without a prescription, drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines), especially the medicines listed below.

- 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

Ask your doctor or pharmacist for advice before taking any medications while you are taking ESBRIET.

PROPER USE OF THIS MEDICATION

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, How Often They Happen and What to Do About Them**)

Usual adult 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:

In case of drug overdose, contact a health care practitioner, 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- **Increased Sensitivity to Sunlight:** skin reactions after going out in the sun or using sunlamps, sunburn
- Skin problems such as **rash**, itchy skin, skin redness, dry skin
- Tiredness, feeling weak or feeling low in energy
- Indigestion, heartburn, acid reflux, loss of appetite, anorexia, 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

If any of these affects you severely, tell your doctor or pharmacist.

ESBRIET may cause liver problems and other abnormal blood test results. To check whether your liver is working properly and your other blood levels you will need blood tests. 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

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			✓
Unknown	Chest pain (angina), slow, fast or irregular heart beats			✓

This is not a complete list of side effects. For any unexpected effects while taking ESBRIET, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Very Common	Increased Sensitivity to Sunlight: skin reaction/rash to sunlight, blistering and/or marked peeling of the skin	✓	
	Diarrhoea	✓	
	Fatigue	✓	
	Persistent Stomach Problems: such as nausea, vomiting	✓	

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
www.rochecanada.com
or by contacting the sponsor, Hoffmann-La Roche Limited, at:
1-888-762-4388.

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