

## PHARMACY

### Drug Information

# Pirfenidone (Esbriet®) Tablets



### What Is Pirfenidone Used to Treat?

- Lungs (pulmonary) fibrosis is a condition where the tissues in your lungs thicken and become stiff and scarred over time. This makes it hard for the lungs to work properly, and causes symptoms such as breathlessness, dry cough and tiredness.
- Pirfenidone is an anti-fibrotic agent used in the treatment of idiopathic pulmonary fibrosis (IPF), where the cause of scarring in the lungs is unknown.
- Pirfenidone may help to slow down the rate of lung scarring.

### How Is Pirfenidone Administered / Taken?

- Pirfenidone is taken in the form of tablets with or after food to reduce stomach upset. It should be taken at the same time each day.
- The tablets should be swallowed whole with water. Do not chew or crush the tablets to reduce the risk of side effects such as nausea and dizziness.
- Do not drink grapefruit juice while taking pirfenidone, as it may prevent this medication from working properly.
- Do not take pirfenidone if you are allergic to pirfenidone or any of the other ingredients of this medicine.
- If you miss a dose, take it as soon as you remember. Never take a double dosage to make up for the missed dose. Resume your next dose at your usual time.
- This drug takes time to work. It may take a few weeks to months before you notice any benefit. It is important that you take your medication regularly as prescribed.

### Can Pirfenidone Be Administered / Taken With Other Medications?

- Do not take pirfenidone if you are taking fluvoxamine (medication used to treat depression and other mood disorders) at the same time.
- It is important that you inform your doctor, pharmacist or nurse about other medications that you are currently taking as they might not work well with pirfenidone. Such medications include over-the-counter medications, supplements and traditional/herbal remedies.

- Some medications known as moderate CYP1A2 inhibitors, such as ciprofloxacin (an antibiotic), can increase the side effects of pirfenidone. You will need to closely observe or avoid this medication if you are taking it at the same time as pirfenidone.

### What Are the Important Side Effects of Pirfenidone?

- Serious side effects are uncommon, but it is important to recognise the side effects of pirfenidone and know how to manage them.
- Always inform your doctor if you experience any side effects.

Side Effects	Management
<ul style="list-style-type: none"> <li>• Nausea</li> <li>• Vomiting</li> <li>• Loss of appetite</li> <li>• Abdominal pain</li> </ul> <p><i>(very common, may affect up to 20-30% of patients)</i></p>	<ul style="list-style-type: none"> <li>• Take medications with or after food.</li> <li>• Do not chew or crush the tablets.</li> </ul>
<p>Diarrhoea</p> <p><i>(very common, may affect up to 25% of patients)</i></p>	<ul style="list-style-type: none"> <li>• The first sign of diarrhoea is when you experience an increased number of watery stools. This could be up to one to three times more than your usual number of bowel movements in a day. You can start taking anti-diarrhoeal medication prescribed by your doctor (e.g. loperamide) and drink plenty of water.</li> <li>• Contact your doctor or pharmacist immediately if diarrhoea becomes severe or does not improve with medication.</li> </ul>
<ul style="list-style-type: none"> <li>• Headache</li> <li>• Fatigue</li> <li>• Difficulty in sleeping</li> </ul> <p><i>(may affect up to 10-20% of patients)</i></p>	<ul style="list-style-type: none"> <li>• Inform your doctor if these side effects become severe or bothersome.</li> </ul>

<p>Upper respiratory tract infections, sinusitis</p> <p><i>(may affect up to 10-20% of patients)</i></p>	<ul style="list-style-type: none"> <li>• Inform your doctor if these side effects are persistent.</li> </ul>
<ul style="list-style-type: none"> <li>• Increased sensitivity to sunlight</li> <li>• Rash</li> </ul> <p><i>(may affect up to 10-30% of patients)</i></p>	<ul style="list-style-type: none"> <li>• Avoid the sun (including sunlamps) where possible while taking this medication.</li> <li>• Wear sunblock daily and cover your arms, legs and head to reduce exposure to sunlight.</li> <li>• Avoid taking tetracycline antibiotics (e.g. doxycycline), which may make you more sensitive to sunlight.</li> </ul>
<p>Liver problems, such as:</p> <ul style="list-style-type: none"> <li>• Yellowing of the white parts of your eyes</li> <li>• Severe abdominal pain</li> <li>• Tea-coloured urine</li> </ul> <p><i>(may affect up to 3-4% of patients)</i></p>	<ul style="list-style-type: none"> <li>• Stop taking pirfenidone. Contact your doctor or pharmacist if these side effects occur.</li> <li>• Your liver function will be checked regularly through blood tests done during your treatment.</li> <li>• Liver function tests will be checked before starting treatment and every month for the first six months. If stable, the tests will be done every 3 months thereafter.</li> </ul>
<p>Signs of infection, such as:</p> <ul style="list-style-type: none"> <li>• Sore throat</li> <li>• Fever</li> <li>• Mouth ulcers</li> <li>• Flu-like symptoms</li> </ul> <p><i>(Rare, may affect up to 1 in 1000 patients)</i></p>	<ul style="list-style-type: none"> <li>• Inform your doctor if these side effects are persistent.</li> <li>• You may need to undergo a blood test to check if your symptoms are related to your medicine.</li> </ul>

Please check with your doctor or pharmacist if you have any other side effects that you think are caused by pirfenidone.

If you develop rashes, facial swelling or shortness of breath after taking pirfenidone, you could be allergic to the medication. Please seek medical attention immediately.

### **Are There Any Special Precautions That I Need to Take?**

- There is no data available about using this medication in pregnant women. Do not take this medicine if you are pregnant, planning to become pregnant or think you might be pregnant. The risk to the unborn child is unknown.
- Please inform your doctor if you intend to conceive or breastfeed while taking this medication. Inform your doctor immediately if pregnancy occurs during your treatment.
- It is also not known if pirfenidone passes into breast milk. If you are breast-feeding, your doctor will discuss with you the risks and benefits of taking this medicine while breast-feeding.
- If you are smoking, you have to stop smoking before you start taking pirfenidone and avoid smoking while you are taking pirfenidone. Smoking will reduce the effectiveness of pirfenidone. Please speak to your doctor or pharmacist if you need help to quit smoking.

### **How Do I Store Pirfenidone?**

- Store your medication in a cool, dry place away from heat, moisture and direct sunlight.

If you have any problem with your treatment, please contact your doctor, pharmacist or nurse clinician.

Please keep all medications out of reach of children.

