

Package leaflet: Information for the user
Esbriet 267 mg film-coated tablets
Esbriet 534 mg film-coated tablets
Esbriet 801 mg film-coated tablets
Pirfenidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Esbriet is and what it is used for
2. What you need to know before you take Esbriet
3. How to take Esbriet
4. Possible side effects
5. How to store Esbriet
6. Contents of the pack and other information

1. What Esbriet is and what it is used for

Esbriet contains the active substance pirfenidone and it is used for the treatment of mild to moderate Idiopathic Pulmonary Fibrosis (IPF) in adults.

IPF is a condition in which the tissues in your lungs become swollen and scarred over time, and as a result makes it difficult to breathe deeply. This makes it hard for your lungs to work properly. Esbriet helps to reduce scarring and swelling in the lungs, and helps you breathe better.

2. What you need to know before you take Esbriet

Do not take Esbriet

- if you are allergic to pirfenidone or any of the other ingredients of this medicine (listed in section 6)
- 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 are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder [OCD])
- if you have severe or end stage liver disease
- if you have severe or end stage kidney disease requiring dialysis.

If any of the above affects you, do not take Esbriet. If you are unsure ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Esbriet

- You may become more sensitive to sunlight (photosensitivity reaction) when taking Esbriet. Avoid the sun (including sunlamps) whilst taking Esbriet. Wear sunblock daily and cover your arms, legs and head to reduce exposure to sunlight (see section 4: Possible side effects).
- You should not take other medicines, such as tetracycline antibiotics (such as doxycycline), which may make you more sensitive to sunlight.
- You should tell your doctor if you suffer from kidney problems

- You should tell your doctor if you suffer from mild to moderate liver problems.
- You should stop smoking before and during treatment with Esbriet. Cigarette smoking can reduce the effect of Esbriet.
- Esbriet may cause dizziness and tiredness. Be careful if you have to take part in activities where you have to be alert and co-ordinated.
- Esbriet can cause weight loss. Your doctor will monitor your weight whilst you are taking this medicine.

Esbriet may cause serious liver problems and some cases have been fatal. You will need a blood test before you start taking Esbriet and at monthly intervals for the first 6 months and then every 3 months thereafter whilst you are taking this medicine to check whether your liver is working properly. It is important that you have these regular blood tests for as long as you are taking Esbriet.

Children and adolescents

Do not give Esbriet to children and adolescents under the age of 18.

Other medicines and Esbriet

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

This is especially important if you are taking the following medicines, as they may change the effect of Esbriet.

Medicines that may increase side effects of Esbriet:

- enoxacin (a type of antibiotic)
- ciprofloxacin (a type of antibiotic)
- amiodarone (used to treat some types of heart disease)
- propafenone (used to treat some types of heart disease)
- fluvoxamine (used to treat depression and obsessive compulsive disorder (OCD)).

Medicines that may reduce how well Esbriet works:

- omeprazole (used in the treatment of conditions such as indigestion, gastroesophageal reflux disease)
- rifampicin (a type of antibiotic).

Esbriet with food and drink

Do not drink grapefruit juice whilst taking this medicine. Grapefruit may prevent Esbriet from working properly.

Pregnancy and breast-feeding

As a precautionary measure, it is preferable to avoid the use of Esbriet if you are pregnant, planning to become pregnant, or think you might be pregnant as the potential risks to the unborn child are unknown.

If you are breast-feeding or plan to breast-feed speak to your doctor or pharmacist before taking Esbriet. As it is unknown whether Esbriet passes into breast milk, your doctor will discuss the risks and benefits of taking this medicine while breast-feeding if you decide to do so.

Driving and using machines

Do not drive or use machines if you feel dizzy or tired after taking Esbriet.

Esbriet contains sodium

Esbriet contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Esbriet

Treatment with Esbriet should be started and overseen by a specialist doctor experienced in the diagnosis and treatment of IPF.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your medicine will usually be given to you in increasing doses as follows:

- for the first 7 days take a dose of 267 mg (1 yellow tablet), 3 times a day with food (a total of 801 mg/day)
- from day 8 to 14 take a dose of 534 mg (2 yellow tablets or 1 orange tablet), 3 times a day with food (a total of 1,602 mg/day)
- from day 15 onwards (maintenance), take a dose of 801 mg (3 yellow tablets or 1 brown tablet), 3 times a day with food (a total of 2,403 mg/day).

The recommended maintenance daily dose of Esbriet is 801 mg (3 yellow tablets or 1 brown tablet) three times a day with food, for a total of 2403 mg/day.

Swallow the tablets whole with a drink of water, during or after a meal to reduce the risk of side effects such as nausea (feeling sick) and dizziness. If symptoms continue, see your doctor.

Dose reduction due to side effects

Your doctor may reduce your dose if you suffer from side effects such as, stomach problems, any skin reactions to sunlight or sun lamps, or significant changes to your liver enzymes.

If you take more Esbriet than you should

Contact your doctor, pharmacist or nearest hospital casualty department immediately if you have taken more tablets than you should, and take your medicine with you.

If you forget to take Esbriet

If you forget a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. Each dose should be separated by at least 3 hours. Do not take more tablets each day than your prescribed daily dose.

If you stop taking Esbriet

In some situations, your doctor may advise you to stop taking Esbriet. If for any reason you have to stop taking Esbriet for more than 14 consecutive days, your doctor will restart your treatment with a dose of 267 mg 3 times a day, gradually increasing this to a dose of 801 mg 3 times a day.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Esbriet and tell your doctor immediately

- If you experience swelling of the face, lips and/or tongue, itching, hives, difficulty breathing or wheezing, or feeling faint, which are signs of angioedema, a serious allergic reaction or anaphylaxis.
- If you experience yellowing of the eyes or skin, or dark urine, potentially accompanied by itching of the skin, pain on the upper right side of your stomach area (abdomen), loss of appetite, bleeding or bruising more easily than normal, or feeling tired. These may be signs of abnormal liver function and could indicate liver injury, which is an uncommon side effect of Esbriet.

Other side effects may include

Talk to your doctor if you get any side effects.

Very common side effects (may affect more than 1 in 10 people):

- skin reactions after going out in the sun or using sunlamps
- feeling sick (nausea)
- tiredness
- diarrhoea
- indigestion or stomach upset
- loss of appetite
- headache.

Common side effects (may affect up to 1 in 10 people):

- infections of the throat or the airways going into the lungs and/or sinusitis
- bladder infections
- weight loss
- difficulty sleeping
- dizziness
- feeling sleepy
- changes in taste
- hot flushes
- shortness of breath
- cough
- stomach problems such as acid reflux, vomiting, feeling bloated, abdominal pain and discomfort, heart burn, feeling constipated and passing wind
- blood tests may show increased levels of liver enzymes
- skin problems such as itchy skin, skin redness or red skin, dry skin, skin rash
- muscle pain, aching joints/joint pains
- feeling weak or feeling low in energy
- chest pain
- sunburn.

Uncommon side effects (may affect up to 1 in 100 people):

- Low levels of sodium in the blood. This may cause headache, dizziness, confusion, weakness, muscle cramps or nausea and vomiting.

Rare side effects (may affect up to 1 in 1,000 people):

- blood tests may show decrease in white blood cells.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Esbriet

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label, blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Esbriet contains

267 mg tablet

The active substance is pirfenidone. Each film-coated tablet contains 267 mg of pirfenidone.

The other ingredients are: microcrystalline cellulose, croscarmellose sodium, povidone K30, colloidal anhydrous silica, magnesium stearate

The film coat consists of: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172)

534 mg tablet

The active substance is pirfenidone. Each film-coated tablet contains 534 mg of pirfenidone.

The other ingredients are: microcrystalline cellulose, croscarmellose sodium, povidone K30, colloidal anhydrous silica, magnesium stearate

The film coat consists of: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172) and iron oxide red (E172)

801 mg tablet

The active substance is pirfenidone. Each film-coated tablet contains 801 mg of pirfenidone.

The other ingredients are: microcrystalline cellulose, croscarmellose sodium, povidone K30, colloidal anhydrous silica, magnesium stearate

The film coat consists of: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide red (E172) and iron oxide black (E172)

What Esbriet looks like and contents of the pack

267 mg tablet

Esbriet 267 mg film-coated tablets are yellow, oval, biconvex film-coated tablets, debossed with “PFD”.

The bottle packs contain one bottle containing 21 tablets, two bottles each containing 21 tablets (42 tablets in total), one bottle containing 42 tablets, one bottle containing 90 tablets, two bottles each containing 90 tablets (180 tablets in total) or one bottle containing 180 tablets.

The blister packs contain 21, 42, 84 or 168 film-coated tablets and the multipacks contain 63 (2-week treatment initiation pack 21+42) or 252 (continuation pack 3x84) film-coated tablets.

The 267 mg blisters strips containing 63 film-coated tablets are each marked with the following symbols and abbreviated names of the day as a reminder to take a dose three times a day:

 (sunrise; morning dose)  (sun; daytime dose) and  (moon; evening dose).

Mon. Tue. Wed. Thu. Fri. Sat. Sun.

534 mg tablet

Esbriet 534 mg film-coated tablets are orange, oval, biconvex film-coated tablets, debossed with “PFD”.

The bottle packs contain either one bottle containing 21 tablets or one bottle containing 90 tablets.

801 mg tablet

Esbriet 801 mg film-coated tablets are brown, oval, biconvex film-coated tablets, debossed with “PFD”.

The bottle pack contains one bottle containing 90 tablets.

The blisters pack contains 84 film-coated tablets and the multipack contains 252 (continuation pack 3x84) film-coated tablets.

The 801 mg blisters strips are each marked with the following symbols and abbreviated names of the day as a reminder to take a dose three times a day:

 (sunrise; morning dose)  (sun; daytime dose) and  (moon; evening dose).

Mon. Tue. Wed. Thu. Fri. Sat. Sun.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Roche Registration GmbH
Emil-Barell-Strasse 1
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Germany

Manufacturer

Roche Pharma AG
Emil-Barell-Str. 1
D-79639 Grenzach-Wyhlen
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Roche Products Ltd.
Tel: +44 (0) 1707 366000

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

There are also links to other websites about rare diseases and treatments.