

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Esbriet[®] 267 mg pirfenidone capsules
Sugar free

Read all of this leaflet carefully before you start taking Esbriet

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Esbriet has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 is indicated for the reduction of progression of mild to moderately severe idiopathic pulmonary fibrosis (IPF) in non-smoking and former-smoking adults.

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 Esbriet,
- if you are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder (OCD)),

- 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 Cytochrome P450 CYP 1A2 inducers, including cigarette smoking,
- if you have severe liver disease,
- if you have severe kidney disease.

Warnings and precautions

Talk to your doctor or nurse before taking Esbriet:

- You may become more sensitive to sunlight (photosensitivity reaction) when taking Esbriet. Avoid the sun (including sunlamps) whilst taking Esbriet. Use a sunblock daily and cover your arms, legs and head to reduce exposure to sunlight.
- 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 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.
- You should tell your doctor if you suffer from mild to moderate kidney problems.
- 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 Esbriet 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.

Other medicines and Esbriet

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional 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:

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

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, used to treat tuberculosis (TB)).

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Esbriet with food and drink

Take Esbriet during or after a meal to reduce the risk of side effects such as nausea (feeling sick) and dizziness.

Pregnancy and breastfeeding

Do not take Esbriet if you are pregnant, planning to become pregnant or think you might be pregnant. The risk to the unborn child is unknown.

If you are breastfeeding, speak to your doctor or pharmacist before taking Esbriet. It is not known if Esbriet passes into breast milk. You must not take Esbriet if you are breastfeeding.

Driving and using machines

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

3. How to take Esbriet

Do not share medicines prescribed for you with any other person.

Always take Esbriet exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your medicine will usually be prescribed for you in increasing doses as follows:

- for the first 7 days: 267 mg (1 capsule), 3 times a day with food.
- from day 8 to 14: 534 mg (2 capsules), 3 times a day with food.
- from day 15 onwards: 801 mg (3 capsules), 3 times a day with food.

Swallow the capsules 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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre, and take your medicine with you.

If you forget to take Esbriet

If you forget a dose take it as soon as you remember, but separate each dose by at least 3 hours.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking Esbriet

Do not stop taking Esbriet unless your doctor tells you to. If for any reason you have to stop taking Esbriet for more than 14 consecutive days, your doctor will restart your treatment with 267 mg (1 capsule) 3 times a day, gradually increasing this to 801 mg (3 capsules) 3 times a day.

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

4. Possible side effects

Esbriet can have side effects. Not all side effects reported for Esbriet are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Esbriet, please consult your doctor, pharmacist or other healthcare professional for advice.

The following serious side effects have been reported and you should stop taking Esbriet and tell your doctor immediately:

- if you experience a serious allergic (hypersensitivity) reaction such as swelling of the face, lips and/or tongue, difficulty breathing or wheezing,
- if you experience a severe skin reaction to sunlight or sunlamps such as blistering and/or peeling of the skin. Avoid the sun (including sunlamps) whilst taking Esbriet, wear sunblock daily and cover your arms, legs and head to reduce exposure to sunlight to limit this reaction,
- if you feel unwell and have yellowing of the eyes or skin, or dark urine, potentially accompanied by itching of the skin,
- if you get signs of an infection such as a sore throat, fever, mouth ulcers or flu-like symptoms.

You may need to have a blood test to check if your symptoms are related to Esbriet.

Other side effects may include

Tell your doctor or pharmacist as soon as possible if you notice any of the following side effects listed below:

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

- decrease in appetite,
- decrease in weight,
- difficulty sleeping,
- headache,
- dizziness,
- indigestion or stomach upset (dyspepsia),
- feeling sick (nausea),
- diarrhoea,
- stomach problems such as acid reflux (gastro-oesophageal reflux disease),

- rash,
- joint pain or aching joints,

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

- changes in taste,
- stomach pain,
- increased levels of liver enzymes, which uncommonly may be fatal
- skin reactions after going out in the sun or using sunlamps,
- itching,
- feeling weak or feeling low in energy.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Esbriet.

5. How to store Esbriet

Keep well closed. Store all medicine out of reach of children.

Store at or below 30 °C in the original container until required for use.

This medicine should not be used after the expiry date (EXP) shown on the pack.

Return all unused medicine to your pharmacist for disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Esbriet contains

Each hard capsule contains 267 mg of the active substance, pirfenidone.

Esbriet is sugar free.

The other ingredients are:

Capsule contents: croscarmellose sodium, magnesium stearate, microcrystalline cellulose and povidone.

Capsule shell: gelatin and titanium dioxide (E171).

Printing ink: ammonium hydroxide, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), isopropyl alcohol, n-butyl alcohol, propylene glycol and shellac glaze.

What Esbriet looks like and contents of the pack

A hard gelatin capsule with a white to off-white opaque body and cap containing a pale yellow powder. The capsule is imprinted with “PFD 267 mg” in brown ink.

Each carton contains a white 250 mL high density polyethylene (HDPE)-container with a foil seal and white HDPE child-resistant closure, containing 270 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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