

Esbriet[®] Tablets

(es-br- ee- et)

Pirfenidone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Esbriet. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Esbriet against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Esbriet is used for

Esbriet contains the active ingredient pirfenidone.

Esbriet is used to treat Idiopathic Pulmonary Fibrosis (IPF).

IPF is a condition in which the tissues in your lungs become swollen and as a result makes it hard for your lungs to work properly.

Esbriet helps to reduce the scarring and swelling in the lungs, and helps you breathe better.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

Before you take Esbriet

When you must not take it

Do not take Esbriet if you have an allergy to:

- any medicine containing pirfenidone
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- Serious skin reactions, including Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms and toxic epidermal necrolysis have been reported in association with Esbriet treatment. Stop using Esbriet and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in the Side Effects section

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known if pirfenidone passes into breast milk. Talk to your doctor or pharmacist before taking Esbriet, your doctor will discuss the risks and benefits of taking this medicine while breast feeding.

Do not give this medicine to a child or adolescents under the age of 18 years.

Safety and effectiveness in children and adolescents younger than 18 years have not been established.

Do not take Esbriet if you are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder (OCD)).

Do not take Esbriet if you have experienced an allergic reaction when previously taking Esbriet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take Esbriet if you have or have had any of the following:

- severe liver problems
- severe kidney problems including dialysis

Do not take Esbriet after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- are a smoker

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Avoid the sun, including sunlamps or tanning beds, while taking Esbriet.

You may become more sensitive to sunlight while taking Esbriet.

It is important to wear sunblock daily and cover your arms legs and head to reduce exposure to sunlight.

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 while you are taking this medicine.

If you have not told your doctor about any of the above, tell him/her before you start taking Esbriet.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Esbriet may interfere with each other. These include:

- fluvoxamine a medicine used to treat depression and OCD.
- tetracyclines (such as doxycycline) medicines used to treat infections and which may make you more sensitive to sunlight
- ciprofloxacin and enoxacin, medicines used to treat infections

- omeprazole, a medicine used in the treatment of indigestion, and stomach ulcers.
- rifampicin a type of antibiotic
- amiodarone, a medicine used to treat some types of heart disease
- propafenone, a medicine used to treat some types of heart disease.

These medicines may be affected by Esbriet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Esbriet

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The recommended dose of Esbriet is:

Days 1 to 7: one 267 mg tablet, three times a day with food

Days 8 to 14: two 267 mg tablets or one 534 mg tablet, three times a day with food

Day 15 onward: three 267 mg tablets or one 801 mg tablet, three times a day with food

How to take it

Swallow the tablets whole with a full glass of water.

If you are having trouble swallowing the tablets talk to your pharmacist

Take Esbriet with or immediately after food.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take Esbriet with or immediately after food.

It is important to take Esbriet with or immediately after food. This will reduce the risks of side effects such as nausea (feeling sick) and dizziness.

Do not drink grapefruit juice while taking Esbriet.

Grapefruit may prevent Esbriet from working properly.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If you forget to take a dose take it as soon as you remember, but separate each dose by 3 hours. Do not take more than 3 doses a day.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Esbriet. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Esbriet

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Esbriet.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to prevent unwanted side effects.

Things you must not do

Do not take Esbriet to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen

If for any reason you have to stop taking Esbriet for more than 14 consecutive days, your doctor will restart your treatment with one 267 mg tablet three times a day, gradually increasing this to three 267 mg tablets or one 801 mg tablet three times a day.

Things to be careful of

Be careful driving or operating machinery until you know how Esbriet affects you.

This medicine may cause dizziness, and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Esbriet can cause low sodium levels in the blood.

Tell your doctor if you experience nausea, headache or dizziness. Your doctor may monitor your sodium levels while you are taking Esbriet.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Esbriet.

This medicine helps most people with IPF, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin reactions after going out in the sun or using sunlamps or tanning beds
- rash or itching
- feeling sick (nausea)
- tiredness
- diarrhoea
- indigestion or stomach upset
- loss of appetite
- headache
- muscle aches or pain

- dizziness

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- infection of the throat or of the airways going into the lungs or/or sinusitis
- weight loss
- difficulty in sleeping
- dizziness
- feeling sleepy
- changes in taste
- stomach problems such as acid reflux, vomiting, feeling bloated, abdominal pain and discomfort, heart burn, feeling constipated and passing wind
- If you experience reddish non-elevated, or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms. These signs and symptoms may indicate Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms or toxic epidermal necrolysis.

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The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea coloured) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal.
- swelling of face, lips and/or tongue, difficulty in breathing or wheezing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Esbriet

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Esbriet or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Esbriet 267 mg film-coated tablets are yellowish white to pale yellow, oval, approximately 1.3 x 0.6. cm biconvex film-coated tablets, debossed with "PFD".

Esbriet 534 mg film-coated tablets brownish orange to reddish orange, oval, approximately 1.6 x 0.8 cm biconvex film-coated tablets, debossed with "PFD".

Esbriet 801 mg film-coated tablets are greyish brown to brownish red, oval, approximately 2 x 0.9 cm biconvex film-coated tablets, debossed with "PFD".

Esbriet 267mg, 534 mg and 801 mg film-coated tablets are available in a bottle containing 90 tablets.

Ingredients

Esbriet contains pirfenidone as the active ingredient.

Inactive ingredients:

- microcrystalline cellulose (460)
- croscarmellose sodium
- colloidal anhydrous silica
- povidone K30
- magnesium stearate

Film coating contains:

- polyvinyl alcohol
- titanium dioxide (171)
- Macrogol 3350
- talc
- iron oxide black (172) (801 mg only)

- iron oxide red (172) (534 mg and 801 mg)
- iron oxide yellow (172) (267 mg and 534 mg)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Distributor

Esbriet is distributed in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information (CMI)

Australian Registration Number:

Esbriet 267 mg film-coated tablets AUST R 282525

Esbriet 534 mg film-coated tablets AUST R 282526*

Esbriet 801 mg film coated tablets AUST R 282527

*Not supplied

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