Package leaflet: Information for the patient
Pirfenidone 267 mg film-coated tablets
Pirfenidone 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 Pirfenidone is and what it is used for
2. What you need to know before you take Pirfenidone
3. How to take Pirfenidone
4. Possible side effects
5. How to store Pirfenidone
6. Contents of the pack and other information

1. What Pirfenidone is and what it is used for

Pirfenidone contains the active substance pirfenidone and it is used for the treatment of 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. Pirfenidone helps to reduce scarring and swelling in the lungs, and helps you breathe better.

2. What you need to know before you take Pirfenidone

Do not take Pirfenidone
- 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 Pirfenidone. If you are unsure ask your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Pirfenidone.
- You may become more sensitive to sunlight (photosensitivity reaction) when taking Pirfenidone. Avoid the sun (including sunlamps) whilst taking Pirfenidone. 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 Pirfenidone.
- Cigarette smoking can reduce the effect of Pirfenidone.
- Pirfenidone may cause dizziness and tiredness. Be careful if you have to take part in activities where you have to be alert and co-ordinated.
- Pirfenidone can cause weight loss. Your doctor will monitor your weight whilst you are taking this medicine.
- Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Pirfenidone treatment. Stop using Pirfenidone and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Pirfenidone may cause serious liver problems and some cases have been fatal. You will need a blood test before you start taking Pirfenidone 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 Pirfenidone.

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

Other medicines and Pirfenidone
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 Pirfenidone.
Medicines that may increase side effects of Pirfenidone:
- 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 Pirfenidone works:
- omeprazole (used in the treatment of conditions such as indigestion, gastroesophageal reflux disease)
- rifampicin (a type of antibiotic).

Pirfenidone with food and drink
Do not drink grapefruit juice whilst taking this medicine. Grapefruit may prevent Pirfenidone from working properly.

Pregnancy and breast-feeding
As a precautionary measure, it is preferable to avoid the use of Pirfenidone 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 Pirfenidone. As it is unknown whether Pirfenidone 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 Pirfenidone.

Pirfenidone contains Lactose
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Important information about Sodium content
Pirfenidone contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially `sodium-free'.

3. How to take Pirfenidone

Treatment with Pirfenidone 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), 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 Pirfenidone 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 Pirfenidone 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 Pirfenidone
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 Pirfenidone
In some situations, your doctor may advise you to stop taking Pirfenidone. If for any reason you have to stop taking Pirfenidone 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 Pirfenidone if you notice any of the following symptoms or signs 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 Pirfenidone.
- 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 or toxic epidermal necrolysis.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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):

- infections of the throat or the airways going into the lungs and/or sinusitis
- feeling sick (nausea)
- stomach problems such as acid reflux, vomiting and feeling constipated
- diarrhoea
- indigestion or stomach upset
- weight loss
- decreased appetite
- difficulty sleeping
- tiredness
- dizziness
- headache
- shortness of breath
- cough
- aching joints/joint pains.

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

- bladder infections
- feeling sleepy
- changes in taste
- hot flushes
- stomach problems such as feeling bloated, abdominal pain and discomfort, heart burn and passing wind
- blood tests may show increased levels of liver enzymes
- skin reactions after going out in the sun or using sunlamps
- skin problems such as itchy skin, skin redness or red skin, dry skin, skin rash
- muscle pain
- 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
- 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 Pirfenidone

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 Pirfenidone contains:
267 mg tablet
The active substance is pirfenidone. Each film-coated tablet contains 267 mg of pirfenidone.
The other ingredients are: Lactose Monohydrate, Croscarmellose Sodium, Hypromellose, Water, purified, Silica, Colloidal Anhydrous, Magnesium Stearate.
The film coating consists of: Polyvinyl Alcohol Part. Hydrolyzed (E 1203), Titanium Dioxide (E 171), Polyethylglycol (Macrogol) (E 1521), Talc (E 553b), Iron Oxide Yellow (E 172)

801 mg tablet
The active substance is pirfenidone. Each film-coated tablet contains 801 mg of pirfenidone.
The other ingredients are: Lactose Monohydrate, Croscarmellose Sodium, Hypromellose, Water, purified, Silica, Colloidal Anhydrous, Magnesium Stearate
The film coating consists of: Polyvinyl Alcohol Part. Hydrolyzed (E 1203), Titanium Dioxide (E 171), Polyethylglycol (Macrogol) (E 1521), Talc (E 553b), Black Iron Oxide/Ferrosoferric Oxide (E 172)

What Pirfenidone looks like and contents of the pack

267 mg tablet

Yellow, Oval, biconvex, film-coated tablet, debossed with “L814” on one side and plain on other side.

1 blister containing 21 film-coated tablets (21 in total)
2 blisters each containing 21 film-coated tablets (42 in total).
3 blisters each containing 21 Film-coated tablets (63 in total).
4 blisters each containing 21 film-coated tablets (84 in total).
8 blisters each containing 21 Film-coated tablets (168 in total).
12 blisters each containing 21 Film-coated tablets (252 in total).

2-week treatment initiation pack: multipack containing 63 (1 pack containing 1 blister of 21 and 1 pack containing 2 blisters of 21) film-coated tablets.

Continuation pack: multipack containing 252 (3 packs each containing 4 blisters of 21) film-coated tablets.

801 mg tablet
Brown, Oval, biconvex, film-coated tablet, debossed with “L812” on one side and plain on other side.

4 blisters each containing 21 film-coated tablets (84 in total)
Continuation pack: multipack containing 252 (3 packs each containing 4 blisters of 21) film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Novumgen Limited
20-22 Wenlock Road, London,
N1 7GU, United Kingdom

The Manufacturer
Cubic Pharmaceuticals Limited
Unit 3, Sextant Park, Neptune Close
Medway City Estate, Rochester,
ME2 4LU, United Kingdom

and

Sciom Limited,
Unit 4, Martinfield Business Centre,
Martinfield, Welwyn Garden City,
AL7 1HG, United Kingdom

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