Package leaflet: Information for the user

Pirfenidone Film-coated Tablets
Pirfenidone 267 mg Film-coated Tablets
Pirfenidone 801 mg Film-coated Tablets

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pirfenidone Film-coated Tablets are and what they are used for

Pirfenidone Film-coated Tablets contain the active substance pirfenidone and are 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. This makes it hard for your lungs to work properly and as a result, makes it difficult to breathe deeply. Pirfenidone Film-coated Tablets help to reduce scarring and swelling in the lungs, and helps you breathe better.

2. What you need to know before you take Pirfenidone Film-coated Tablets

Do not take Pirfenidone Film-coated Tablets
- if you are allergic to pirfenidone or any of the other ingredients of this medicine (listed in section 6).
- if you have previously experienced an allergic reaction to 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 Film-coated Tablets. If you are unsure, ask your doctor or pharmacist.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Pirfenidone Film-coated Tablets
- if you suffer from kidney problems
- if you suffer from mild to moderate liver problems.
- Pirfenidone Film-coated Tablets may cause serious liver problems and some cases have been fatal.

You will need a blood test before you start taking Pirfenidone Film-coated Tablets 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 Film-coated Tablets.

- You may become more sensitive to sunlight (photosensitivity reaction) when taking Pirfenidone Film-coated Tablets. Avoid the sun (including sunlamps) whilst taking Pirfenidone Film-coated Tablets. 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 stop smoking before and during treatment with Pirfenidone Film-coated Tablets. Cigarette smoking can reduce the effect of Pirfenidone Film-coated Tablets.
- Pirfenidone Film-coated Tablets 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 Film-coated Tablets 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 Film-coated Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Children and adolescents
Do not give Pirfenidone Film-coated Tablets to children and adolescents under the age of 18.

Other medicines and Pirfenidone Film-coated Tablets

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 Film-coated Tablets.

Medicines that may increase side effects of Pirfenidone Film-coated Tablets:
- 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)). **Do not take** Pirfenidone Film-coated Tablets if you are taking fluvoxamine.
- doxycycline (or other tetracycline antibiotic)

Medicines that may reduce how well Pirfenidone Film-coated Tablets work:
- omeprazole (used in the treatment of conditions such as indigestion, gastroesophageal reflux disease)
- rifampicin (a type of antibiotic).

Pirfenidone Film-coated Tablets with food and drink
Do not drink grapefruit juice whilst taking this medicine. Grapefruit may stop Pirfenidone Film-coated Tablets from working properly.

Pregnancy and breast feeding
As a precaution, it is preferable to avoid the use of Pirfenidone Film-coated Tablets 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 Film-coated Tablets. 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 Film-coated Tablets.

Pirfenidone Film-coated Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. is essentially 'sodium-free'.

3. How to take Pirfenidone Film-coated Tablets

Treatment with Pirfenidone Film-coated Tablets 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 267 mg dose (One 267 mg film-coated tablet), three times a day with food (a total of 801 mg/day).
- **From day 8 to 14:** Take a 534 mg dose (Two 267 film-coated tablets), three times a day with food (a total of 1,602 mg/day).
- **From day 15 onwards** (recommended maintenance dose): Take an 801 mg dose (Three 267 mg film-coated tablets or one 801 mg tablet), three times a day with food (a total of 2,403 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 such side effects, 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 Film-coated Tablets 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 Film-coated Tablets
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 Film-coated Tablets
In some situations, your doctor may advise you to stop taking Pirfenidone Film-coated Tablets. If for any reason you have to stop taking Pirfenidone Film-coated Tablets for more than 14 days in a row, your doctor will restart your treatment with a dose of 267 mg three times a day, gradually increasing this to a dose of 801 mg three 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 Film-coated Tablets and seek medical attention immediately if you notice any of the following symptoms or signs

- Swelling of the face, lips and/or tongue, itching, hives (red, itchy, and swollen areas (welts) on the skin), difficulty breathing or wheezing, or feeling faint, which are signs of, a serious allergic reaction or anaphylaxis.
- 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 Film-coated Tablets.
- 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 (Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Talk to your doctor or pharmacist if you get any of the following side effects or any possible side effects not listed in this leaflet.

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 acid reflux, being sick (vomiting), feeling bloated, abdominal pain and discomfort, heart burn, feeling constipated 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 feeling sick (nausea) and being sick (vomiting).
- blood tests may show decrease in white blood cells

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pirfenidone Film-coated Tablets

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 blister and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Pirfenidone Film-coated Tablets contains

Pirfenidone 267 mg Film-coated Tablets:
- The active substance is pirfenidone.
- Each film-coated tablet contains 267 mg of pirfenidone
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide and sodium stearyl fumarate.
- The film coat consists of: polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc and iron oxide yellow (E172).

Pirfenidone 801 mg Film-coated Tablets:
- The active substance is pirfenidone.
- Each film-coated tablet contains 801 mg of pirfenidone
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, povidone, colloidal silicon dioxide and sodium stearyl fumarate.
- The film coat consists of: polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc. iron oxide black (E172), and iron oxide red (E172).

What Pirfenidone Film-coated Tablets looks like and contents of the pack

Pirfenidone 267 mg Film-coated Tablets are light yellow to yellow coloured, oval shaped tablets, debossed with “A106” on one side and plain on the other side.

The blister packs contain 21, 42, 84 or 168 film-coated tablets. The 2-week treatment initiation pack contains 63 (3 blisters of 21) film-coated tablets and the continuation pack contains 252 (12 blisters of 21) film-coated tablets.

The 267 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.

Pirfenidone 801 mg Film-coated Tablets are light brown to brown coloured, oval shaped tablets, debossed with “A108” on one side and plain on the other side.

The blister packs contain 21, 63 or 84 film-coated tablets. The continuation pack contains 252 (12 blisters of 21) 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.

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