Package leaflet: Information for the user

Pirfenidone APS 267 mg Film-coated tablets
Pirfenidone APS 534 mg Film-coated tablets
Pirfenidone APS 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 APS is and what it is used for

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

2. What you need to know before you take Pirfenidone APS

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

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

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

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

Other medicines and Pirfenidone APS
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 APS.

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

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

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

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

Pirfenidone APS 534 mg contains sunset yellow FCF aluminium lake (E110) which may cause allergic reactions.

3. How to take Pirfenidone APS

Treatment with Pirfenidone APS 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 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 APS 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 APS
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 APS
In some situations, your doctor may advise you to stop taking Pirfenidone APS. If for any reason you have to stop taking Pirfenidone APS 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 APS 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.

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 via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pirfenidone APS

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

Do not use this medicine after the expiry date which is stated on 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 APS contains

267 mg film-coated tablets
The active substance is pirfenidone. Each film-coated tablet contains 267 mg of pirfenidone.
The other ingredients are: mannitol (E421), croscarmellose sodium, povidone K29-32, microcrystalline cellulose, colloidal anhydrous silica, sodium stearyl fumarate.
The film coat consists of: polyvinyl alcohol part hydrolyzed, titanium dioxide (E171), macrogol (E1521) MW 3350, talc and iron oxide yellow (E172).

534 mg film-coated tablets
The active substance is pirfenidone. Each film-coated tablet contains 534 mg of pirfenidone.
The other ingredients are: mannitol (E421), croscarmellose sodium, povidone K29-32, microcrystalline cellulose, colloidal anhydrous silica, sodium stearyl fumarate.
The film coat consists of: polyvinyl alcohol part hydrolyzed, titanium dioxide (E171), macrogol (E1521) MW 3350, talc and sunset yellow FCF aluminium lake (E110) (see section 2).

801 mg film-coated tablets
The active substance is pirfenidone. Each film-coated tablet contains 801 mg of pirfenidone.
The other ingredients are: mannitol (E421), croscarmellose sodium, povidone K29-32, microcrystalline cellulose, colloidal anhydrous silica, sodium stearyl fumarate.
The film coat consists of: polyvinyl alcohol part hydrolyzed, titanium dioxide (E171), macrogol (E1521) MW 3350, talc, iron oxide red (E172) and iron oxide black (E172).

What Pirfenidone APS looks like and contents of the pack

267 mg tablet
Pirfenidone APS 267 mg film-coated tablets are yellow colored, oval shaped, biconvex film-coated tablets debossed with "LP2" on one side and plain on other side.
Blisters contain 63 or 252 film-coated tablets and perforated unit dose blister packs 63 x 1 or 252 x 1 film-coated tablet.

534 mg tablet
Pirfenidone APS 534 mg film-coated tablets are orange colored, oval shaped, biconvex film-coated tablets debossed with "LP5" on one side and plain on other side.
Blisters contain 252 film-coated tablets and perforated unit dose blister packs 252 x 1 film-coated tablet.

801 mg tablet
Pirfenidone APS 801 mg film-coated tablets are brown colored, oval shaped, biconvex film-coated tablets debossed with "LP8" on one side and plain on other side.
Blisters contain 63, 84 or 252 film-coated tablets and perforated unit dose blister packs 63 x 1, 84 x 1 or 252 x 1 film-coated tablet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

axunio Pharma GmbH
Van-der-Smissen-Straße 1
22767 Hamburg
Germany

Manufacturer

Delorbis Pharmaceuticals Ltd.
17 Athinon Str., Ergates Industrial Area
2643 Ergates, Lefkosia
Cyprus

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