PACKAGE LEAFLET

Package leaflet: Information for the user

Pirfenidone Accord 267 mg film-coated tablets
Pirfenidone Accord 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 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 or 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 Accord is and what it is used for

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

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

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Pirfenidone Accord.
- You may become more sensitive to sunlight (photosensitivity reaction) when taking Pirfenidone Accord. Avoid the sun (including sunlamps) whilst taking Pirfenidone Accord.

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 Accord. Cigarette smoking can reduce the effect of Pirfenidone Accord.
- Pirfenidone Accord 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 Accord 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 Accord treatment. Stop using Pirfenidone Accord and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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

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

Other medicines and Pirfenidone Accord
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 Accord.

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

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

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

Pirfenidone Accord contains lactose
Pirfenidone Accord contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Pirfenidone Accord

Treatment with Pirfenidone Accord 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 Accord 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.

<u>Dose reduction due to side effects</u>
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 Accord 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 Accord
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 Accord
In some situations, your doctor may advise you to stop taking Pirfenidone Accord. If for any reason you have to stop taking Pirfenidone Accord 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 Accord 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, difficulty breathing or wheezing, or feeling faint, which are signs of angioedema, 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 Accord.
- 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).

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 Accord

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 carton and the blister 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 to protect the environment.

6. Contents of the pack and other information

What Pirfenidone Accord contains

267 mg tablet
The active substance is pirfenidone. Each film-coated tablet contains 267 mg of pirfenidone.
The other ingredients are: lactose monohydrate, copovidone, croscarmellose sodium (E468), magnesium stearate (E572)
The film coat consists of: Poly(vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), iron oxide yellow (E172)

801 mg tablet
The active substance is pirfenidone. Each film-coated tablet contains 801 mg of pirfenidone.
The other ingredients are: lactose monohydrate, copovidone, croscarmellose sodium (E468), magnesium stearate (E572)
The film coat consists of: Poly (vinyl alcohol) (E1203), titanium dioxide (E171), macrogol 4000(E1521), talc (E553b), iron oxide black (E172), iron oxide red (E172)

What Pirfenidone Accord looks like and contents of the pack

267 mg tablet
Pirfenidone Accord 267 mg film-coated tablets are yellow, oval, biconvex, bevel-edged, film coated tablets debossed with "D1" on one side and plain on other side with dimension of 13 x 7 mm.

801 mg tablet
Pirfenidone Accord 801 mg film-coated tablets are brown, oval, biconvex, bevel-edged, film coated tablets debossed with "D2" on one side and plain on other side with dimension of 21 x 10 mm.

Pirfenidone Accord 801 mg film-coated tablets are supplied in PVC/PE/ PCTFE aluminium foil blister and PVC/PE/ PCTFE aluminium foil perforated unit-dose blister with below pack sizes:

267 mg tablet

Pack sizes: 21, 42, 84, 168 film-coated tablets or 21x1, 42x1, 84x1, 168x1 perforated unit-dose film-coated tablets.

2-week treatment initiation pack:
Each multipack contains 63 film-coated tablets in total. (*1 pack containing 1 blister of 21 and 1 pack containing 2 blisters of 21 film-coated tablets or 1 pack containing a 21x1 and a 42x1 perforated unit dose blisters of film-coated tablets)*

Continuation pack:
Each multipack contains 252 film-coated tablets in total. (*3 packs each containing 4 blisters of 21 film-coated tablets or 3 packs each containing 84 x 1 perforated unit dose blisters of film-coated tablets)*

801 mg tablet
Pack sizes: 84 film-coated tablets or 84x1 perforated unit-dose film-coated tablets.

Continuation pack:
Each multipack contains 252 film-coated tablets in total. *(3 packs each containing 4 blisters of 21 film-coated tablets or 3 packs each containing 84 x 1 perforated unit dose blisters of film-coated tablets.)*

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Laboratori Fundació Dau
C/ C, 12-14 Pol.
Ind. Zona Franca,
Barcelona, 08040, Spain

Accord Healthcare Polska Sp. z o.o.

Ul. Lutomierska 50, 95-200,
Pabianice, Poland

Accord Healthcare B.V.
Winthontlaan 200, 3526 KV
Utrecht, Netherland

Pharmadox Healthcare Limited
KW20A Kordin
Industrial Park,
Paola PLA 3000, Malta

This medicine is authorized in the Member States of the European Economic Area (EEA) under the following names:

Name of Member State	**Name of the medicinal product**
Netherlands	Pirfenidone Accord 267 mg/801 mg Filmomhulde tabletten
Germany	Pirfenidon Accord 267 mg/801 mg Filmtabletten
Denmark	Pirfenidone Accord
Norway	Pirfenidone Accord
Sweden	Pirfenidone Accord
Finland	Pirfenidone Accord
Spain	Pirfenidone Accord 267 mg/801 mg comprimidos recubiertos con película
Italy	Pirfenidone Accord
Austria	Pirfenidon Accord 267 mg/801 mg Filmtabletten
Belgium	Pirfenidone Accord 267 mg/801 mg Filmtabletten
Estonia	Pirfenidone Accord
Lithuania	Pirfenidone Accord 267 mg plėvele dengtos tabletės Pirfenidone Accord 801 mg plėvele dengtos tabletės
Latvia	Pirfenidone Accord 267 mg/801 mg apvalkotās tabletes
Cyprus	PIRFENIDONE ACCORD
Greece	PIRFENIDONE ACCORD
Portugal	Pirfenidone Accord
Poland	Pirfenidone Accord
Croatia	Pirfenidon Accord 267 mg filmom obložene tablete Pirfenidon Accord 801 mg filmom obložene tablete
Czech Republic	Pirfenidone Accord
Slovenia	Pirfenidon Accord 267 mg/801 mg filmsko obložene tablete
Slovakia	Pirfenidón Accord 267 mg/801 mg
Ireland	Pirfenidone Accord 267 mg/801 mg film-coated tablets
France	PIRFENIDONE ACCORD 267mg, comprimé pelliculé PIRFENIDONE ACCORD 801mg, comprimé pelliculé

This leaflet was last revised in 11/2024.