

Package leaflet: Information for the user

Pirfenidone Clonmel 267 mg film-coated tablets Pirfenidone Clonmel 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

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1. What Pirfenidone Clonmel is and what it is used for

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

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

DO NOT take Pirfenidone Clonmel

- 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 Clonmel. If you are unsure ask your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Pirfenidone Clonmel.

- You may become more sensitive to sunlight (photosensitivity reaction) when taking Pirfenidone Clonmel. Avoid the sun (including sunlamps) whilst taking Pirfenidone Clonmel. 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 Clonmel. Cigarette smoking

can reduce the effect of Pirfenidone Clonmel.

- Pirfenidone Clonmel 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 Clonmel 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 Clonmel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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

Children and adolescents

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

Other medicines and Pirfenidone Clonmel

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 Clonmel.

Medicines that may increase side effects of Pirfenidone Clonmel:

- 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 Clonmel works:

- omeprazole (used in the treatment of conditions such as indigestion, gastroesophageal reflux disease)
- rifampicin (a type of antibiotic)

Pirfenidone Clonmel with food and drink

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

Pregnancy and breast-feeding

As a precautionary measure, it is preferable to avoid the use of Pirfenidone Clonmel 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 Clonmel. 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 Clonmel.

Pirfenidone Clonmel contains sodium

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

Pirfenidone Clonmel 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.

3. How to take Pirfenidone Clonmel

Treatment with Pirfenidone Clonmel 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)
In countries where the 534 mg strength is not available:
- 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 2 403 mg/day.

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 sunlamps, or significant changes to your liver enzymes.

Method of administration

Pirfenidone Clonmel is for oral use. 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.

If you take more Pirfenidone Clonmel 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 Clonmel

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 Clonmel

In some situations, your doctor may advise you to stop taking Pirfenidone Clonmel. If for any reason you have to stop taking Pirfenidone Clonmel for more than 14 consecutive days, your doctor will restart your treatment with a dose of 267 mg (1 yellow tablet) 3 times a day, gradually increasing this to a dose of 801 mg (3 yellow tablets or 1 brown tablet) 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 Clonmel 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 Clonmel.
- 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 pain

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 Clonmel

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 Clonmel contains

267 mg tablet

The active substance is pirfenidone. Each tablet contains 267 mg of pirfenidone.

The other ingredients are: lactose monohydrate, croscarmellose sodium, hypromellose, silica colloidal anhydrous and magnesium stearate.

Film coating: Polyvinyl Alcohol, partially hydrolysed, Titanium Dioxide (E171), Macrogol 3350, Talc and Iron Oxide Yellow (E172).

801 mg tablet

The active substance is pirfenidone. Each tablet contains 801 mg of pirfenidone.

The other ingredients are: lactose monohydrate, croscarmellose sodium, hypromellose, silica colloidal anhydrous and magnesium stearate.

Film coating: Polyvinyl Alcohol, partially hydrolysed, Titanium Dioxide (E171), Macrogol 3350, Talc, Black Iron Oxide (E172) and Iron Oxide Red (E172).

What Pirfenidone Clonmel looks like and contents of the pack

Film-coated tablet

Pirfenidone Clonmel 267 mg film-coated tablets are yellow, oval, biconvex, debossed with “L814” on one side and plain on other side. Approximately 13.3 mm in length and 6.5 mm in width.

Pirfenidone Clonmel 801 mg film-coated tablets are brown, oval, biconvex, debossed with “L812” on one side and plain on other side. Approximately 20.0 mm in length and 9.2 mm in width.

Pirfenidone Clonmel 267 mg is available in blisters in packs containing 21, 63, 84, 90, 168, 180, 252 or 270 film-coated tablets.

Pirfenidone Clonmel 801 mg is available in blisters in packs containing 21, 63, 84, 90, 168, 180, 252 or 270 film-coated tablets.

Pirfenidone Clonmel 267 mg is available in unit-dose blisters in packs containing 21x1, 63x1, 84x1, 90x1, 168x1, 180x1, 252x1 or 270x1 film-coated tablets.

Pirfenidone Clonmel 801 mg is available in unit-dose blisters in packs containing 21x1, 63x1, 84x1, 90x1, 168x1, 180x1, 252x1 or 270x1 film-coated tablets.

Pirfenidone Clonmel 267 mg is available in bottles in packs containing 21, 90 or 180 film-coated tablets.

Pirfenidone Clonmel 801 mg is available in bottles in packs containing 90 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

- Belgium: Pirfenidon EG 267 mg filmomhulde tabletten
Pirfenidon EG 534 mg filmomhulde tabletten
Pirfenidon EG 801 mg filmomhulde tabletten
- Denmark: Pirfenidone STADA
- Finland: Pirfenidone STADA 267 mg kalvopäällysteiset tabletit
Pirfenidone STADA 801 mg kalvopäällysteiset tabletit
- France: PIRFENIDONE EG 267 mg, comprimé pelliculé
PIRFENIDONE EG 801 mg, comprimé pelliculé
- Germany: Pirfenidon STADA 267 mg Filmtabletten
Pirfenidon STADA 534 mg Filmtabletten
Pirfenidon STADA 801 mg Filmtabletten
- Ireland: Pirfenidone Clonmel 267 mg film-coated tablets
Pirfenidone Clonmel 801 mg film-coated tablets
- Luxembourg: Pirfenidon EG 267 mg comprimés pelliculés
Pirfenidon EG 534 mg comprimés pelliculés
Pirfenidon EG 801mg comprimés pelliculés
- Netherlands: Pirfenidon CF 267 mg, filmomhulde tabletten
Pirfenidon CF 801 mg, filmomhulde tabletten
- Norway: Pirfenidone STADA
- Poland: Pirfenidone STADA
- Spain: Pirfenidona STADA 267 mg comprimidos recubiertos con película EFG
Pirfenidona STADA 534 mg comprimidos recubiertos con película EFG
Pirfenidona STADA 801 mg comprimidos recubiertos con película EFG
- Sweden: Pirfenidone STADA 267 mg filmdragerade tabletter
Pirfenidone STADA 801 mg filmdragerade tabletter

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