

PIRFENIDET

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking PIRFENIDET?

PIRFENIDET contains the active ingredient Pirfenidone. PIRFENIDET is used to treat Idiopathic Pulmonary Fibrosis (IPF).

For more information, see Section [1. Why am I using PIRFENIDET?](#) in the full CMI.

2. What should I know before I take PIRFENIDET?

Do not use if you have ever had an allergic reaction to PIRFENIDET or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PIRFENIDET?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PIRFENIDET and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take PIRFENIDET?

- Upon initiating treatment, your doctor will explain the appropriate dose for the first 7 days, then the appropriate dose for days 8 to 14, and finally the appropriate dose for day 15 and onwards

More instructions can be found in Section [4. How do I use PIRFENIDET?](#) in the full CMI.

5. What should I know while using PIRFENIDET?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking PIRFENIDET.• Avoid the sun, including sunlamps or tanning beds,• Do not drink grapefruit juice• stop smoking before and during treatment
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• PIRFENIDET may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol
Looking after your medicine	<ul style="list-style-type: none">• Keep the tablets in a cool dry place where the temperature stays below 25 °C.

For more information, see Section [5. What should I know while using PIRFENIDET?](#) in the full CMI.

6. Are there any side effects?

Call your doctor immediately or go to the nearest emergency department if you develop (Jaundice) yellowing of the skin or the white part of the eyes, dark or brown urine, pain in the upper right side of the stomach area, bleeding or bruising more easily than normal. Or if you have an allergic reaction with swelling of the face, lips, and/or tongue, difficulty in breathing or wheezing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PIRFENIDET

Active ingredient(s): *Pirfenidone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PIRFENIDET. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PIRFENIDET.**

Where to find information in this leaflet:

- [1. Why am I taking PIRFENIDET?](#)
- [2. What should I know before I take PIRFENIDET?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take PIRFENIDET?](#)
- [5. What should I know while taking PIRFENIDET?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking PIRFENIDET?

PIRFENIDET contains the active ingredient Pirfenidone. PIRFENIDET is used to treat Idiopathic Pulmonary Fibrosis (IPF). IPF is a condition in which the tissues in your lungs become swollen and as a result makes it hard for your lungs to work properly. PIRFENIDET helps to reduce the scarring and swelling in the lungs, and helps you breathe better.

PIRFENIDET is used to treat Idiopathic Pulmonary Fibrosis (IPF).

Your doctor may have prescribed PIRFENIDET for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I take PIRFENIDET?

Warnings

Do not take PIRFENIDET if:

- you are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder (OCD)).
- you have or have had any of the following:
 - severe liver problems
 - severe kidney problems including dialysis
- you are allergic to Pirfenidone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin
- Do not give this medicine to a child or adolescent under the age of 18 years. Safety and effectiveness in children and adolescents less than 18 years old have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions
 - Kidney problems
 - Liver problems
 - Are a smoker

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant or are breast feeding. Your doctor can discuss with you the risks and benefits involved.

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known if pirfenidone passes into breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PIRFENIDET may interfere with each other. These include:

- fluvoxamine a medicine used to treat depression and OCD.
- tetracyclines (such as doxycycline) medicines used to treat infections and which may make you more sensitive to sunlight
- ciprofloxacin and enoxacin, medicines used to treat infections
- omeprazole, a medicine used in the treatment of indigestion, and stomach ulcers.
- rifampicin a type of antibiotic
- amiodarone, a medicine used to treat some types of heart disease
- propafenone, a medicine used to treat some types of heart disease.

These medicines may be affected by PIRFENIDET or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PIRFENIDET.

4. How do I take PIRFENIDET?

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions, ask your doctor or pharmacist for help.

Upon initiating treatment, the dose should be titrated to the recommended daily dose of 2403 mg/ day over a 14 day period as follows:

- Days 1 to 7: a dose of 267 mg administered three times a day (801 mg/day)
- Days 8 to 14: a dose of 534 mg administered three times a day (1602 mg/day)
- Day 15 onward: a dose of 801 mg administered three times a day (2403 mg/day)

Doses above 2403 mg/day are not recommended for any patient.

- Take PIRFENIDET with or immediately after food.
- Swallow the tablets whole with a full glass of water.
- If you are having trouble swallowing the tablets talk to your pharmacist

When to take PIRFENIDET

- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- **Take PIRFENIDET with or immediately after food.** It is important to take PIRFENIDET with or immediately after food. This will reduce the risks of side effects such as nausea (feeling sick) and dizziness.

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take PIRFENIDET

PIRFENIDET should be used regularly at the same time each day. If you miss your dose at the usual time,

- **take it as soon as you remember, but separate each dose by 3 hours.**
- **Do not take more than 3 doses a day.**
- **Do not take a double dose to make up for the dose that you missed.**
- If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much PIRFENIDET

If you think that you have used too much PIRFENIDET, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking PIRFENIDET?

Things you should do

Avoid the sun, including sunlamps or tanning beds, while taking PIRFENIDET. You may become more sensitive to sunlight while taking PIRFENIDET. It is important to wear sunblock daily and cover your arms legs and head to reduce exposure to sunlight.

Do not drink grapefruit juice while taking PIRFENIDET. Grapefruit may prevent PIRFENIDET from working properly.

You should stop smoking before and during treatment with PIRFENIDET. Cigarette smoking can reduce the effect of PIRFENIDET.

PIRFENIDET may cause dizziness and tiredness. Be careful if you have to take part in activities where you have to be alert and co-ordinated.

PIRFENIDET can cause weight loss. Your doctor will monitor your weight while you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to prevent unwanted side effects.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Call your doctor straight away if you:

- If you become pregnant while taking this medicine, tell your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are using PIRFENIDET.

Things you should not do

- **Do not stop taking this medicine or lower the dosage without checking with your doctor.** If you stop taking it suddenly, your condition may worsen. If for any reason you have to stop taking PIRFENIDET for more than 14 consecutive days, your doctor will restart your treatment with one 267 mg tablet three times a day, gradually increasing this to three 267 mg tablets or one 801 mg tablet three times a day.
- Do not take PIRFENIDET to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PIRFENIDET affects you.

PIRFENIDET may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep the tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they may not keep well.

- Keep the tablets in a cool dry place where the temperature stays below 25 °C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders:</p> <ul style="list-style-type: none"> • tiredness • dizziness • headache • muscle aches or pain <p>Skin and subcutaneous tissue disorders:</p> <ul style="list-style-type: none"> • skin reactions after going out in the sun or using sunlamps or tanning beds • rash or itching <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • nausea • diarrhoea • indigestion of stomach upset • loss of appetite 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<p>Respiratory tract disorders:</p> <ul style="list-style-type: none"> • infection of the throat or of the airways going into the lungs and/or sinusitis <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • acid reflux • vomiting • feeling bloated • abdominal pain and discomfort • heart burn • feeling constipated • passing wind 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • changes in taste <p>General disorders:</p> <ul style="list-style-type: none"> • weight loss • difficulty in sleeping • dizziness • feeling sleepy 	

Serious side effects

Serious side effects	What to do
<p>General disorder:</p> <ul style="list-style-type: none"> • Jaundice; yellowing of the skin or the white part of the eyes, dark or brown urine, pain in the upper right side of the stomach area, bleeding or bruising more easily than normal • Swelling of the face, lips, and/or tongue, difficulty in breathing or wheezing 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PIRFENIDET contains

Active ingredient (main ingredient)	Pirfenidone
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Lactose monohydrate • croscarmellose sodium • colloidal anhydrous silica • magnesium stearate • Copovidone <p>Film coating contains:</p> <ul style="list-style-type: none"> • For 267 mg tablets, OPADRY II Complete Film Coating System 85F520195 YELLOW. Coating contains: <ul style="list-style-type: none"> ○ Polyvinyl alcohol ○ Macrogol 3350 ○ Talc ○ Titanium dioxide ○ Iron oxide yellow

	<ul style="list-style-type: none"> • For 801 mg tablets, OPADRY II Complete Film Coating System 32K540099 PURPLE. Coating contains: <ul style="list-style-type: none"> ○ Polyvinyl alcohol ○ Macrogol 3350 ○ Talc ○ Titanium dioxide ○ Iron oxide black ○ Iron oxide red
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What PIRFENIDET looks like

PIRFENIDET 267 mg tablets are yellow, oval, biconvex, bevel-edged film coated tablets debossed with “D1” on one side and plain on other side.

PIRFENIDET 801 mg tablets are brown, oval, biconvex, bevel-edged film coated tablets debossed with “D2” on one side and plain on other side.

Who distributes PIRFENIDET

Sponsor

Accord Healthcare

Level 24, 570 Bourke Street Melbourne

VIC 3000

Phone: 1800 134 988

Email: ds@commercialeyes.com.au

Distributor

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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