

PIRFENIDONE SANDOZ®

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 using PIRFENIDONE SANDOZ?

PIRFENIDONE SANDOZ contains the active ingredient pirfenidone. PIRFENIDONE SANDOZ is used to treat Idiopathic Pulmonary Fibrosis (IPF).

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

2. What should I know before I use PIRFENIDONE SANDOZ?

Do not use PIRFENIDONE SANDOZ if you have ever had an allergic reaction to pirfenidone 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 PIRFENIDONE SANDOZ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PIRFENIDONE SANDOZ 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 use PIRFENIDONE SANDOZ?

- The recommended dose of PIRFENIDONE SANDOZ is:
 - Days 1 to 7:** one 267 mg tablet, three times a day with food
 - Days 8 to 14:** two 267 mg tablets or one 534 mg tablet, three times a day with food
 - Day 15 onward:** three 267 mg tablets or one 801 mg tablet, three times a day with food

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

5. What should I know while using PIRFENIDONE SANDOZ?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using PIRFENIDONE SANDOZ.PIRFENIDONE SANDOZ can cause low sodium levels in the blood. Tell your doctor if you experience nausea, headache or dizziness. Your doctor may monitor your sodium levels while you are taking PIRFENIDONE SANDOZ.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">PIRFENIDONE SANDOZ 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">Store below 30°C.

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

6. Are there any side effects?

Common side effects: rash or itching, diarrhoea, feeling sick (nausea), indigestion or stomach upset, loss of appetite, headache

Serious side effects: yellowing of your skin or the white part of your eyes (jaundice), dark or brown urine, infection of the throat or of the airways going into the lungs or sinusitis

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.

PIRFENIDONE SANDOZ®

Active ingredient(s): *pirfenidone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PIRFENIDONE SANDOZ. **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 PIRFENIDONE SANDOZ.**

Where to find information in this leaflet:

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

1. Why am I using PIRFENIDONE SANDOZ?

PIRFENIDONE SANDOZ contains the active ingredient **pirfenidone**.

PIRFENIDONE SANDOZ is used to treat **Idiopathic Pulmonary Fibrosis (IPF)**. PIRFENIDONE SANDOZ helps to reduce the scarring and swelling in the lungs, and helps you breathe better.

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

2. What should I know before I use PIRFENIDONE SANDOZ?

Warnings

Do not use PIRFENIDONE SANDOZ if:

- 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 use this medicine. Some of the symptoms of an allergic reaction 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
- 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
- it is 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 any other medical conditions
 - kidney problems
 - liver problems
- are a smoker
- take any medicines for any other condition

Serious skin reactions, including Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms and toxic epidermal necrolysis have been reported in association with pirfenidone treatment. Stop using PIRFENIDONE SANDOZ and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in Section [6. Are there any side effects?](#)

Avoid the sun, including sunlamps or tanning beds, whilst taking PIRFENIDONE SANDOZ.

You may become more sensitive to sunlight while taking PIRFENIDONE SANDOZ. It is important to wear sunblock daily and cover your arms, legs and head to reduce exposure to sunlight.

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

PIRFENIDONE SANDOZ may cause dizziness and tiredness. Be careful if you have to take part in activities where you have to be alert and coordinated.

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

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if pirfenidone passes into breast milk. Talk to your doctor or pharmacist before taking PIRFENIDONE SANDOZ, your doctor will discuss the risks and benefits of taking this medicine while breast feeding.

Use in Children

Do not give this medicine to a child or adolescents under the age of 18 years.

- Safety and effectiveness in children and adolescents younger than 18 years have not been established.

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 may interfere with PIRFENIDONE SANDOZ and affect how it works. 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 Pirfenidone Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How do I use PIRFENIDONE SANDOZ?

How much to take

- The recommended dose of PIRFENIDONE SANDOZ is:
Days 1 to 7: one 267 mg tablet, three times a day with food
Days 8 to 14: two 267 mg tablets or one 534 mg tablet, three times a day with food
Day 15 onward: three 267 mg tablets or one 801 mg tablet, three times a day with food

When to take PIRFENIDONE SANDOZ

- PIRFENIDONE SANDOZ should be used 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.

How to take PIRFENIDONE SANDOZ

- **Swallow the tablets whole with a full glass of water.** If you are having trouble swallowing the tablets, talk to your pharmacist.
- **Take PIRFENIDONE SANDOZ with or immediately after food.**
It is important to take PIRFENIDONE SANDOZ with or immediately after food. This will reduce the risks of side effects such as nausea (feeling sick) and dizziness.
- **Do not drink grapefruit juice while taking PIRFENIDONE SANDOZ.**

Grapefruit may prevent PIRFENIDONE SANDOZ from working properly.

How to long to take PIRFENIDONE SANDOZ

- Continue taking your medicine for as long as your doctor tells you to.
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 use PIRFENIDONE SANDOZ

PIRFENIDONE SANDOZ should be used regularly at the same time each day.

If you forget to take a dose, 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 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 use too much PIRFENIDONE SANDOZ

If you think that you have used too much PIRFENIDONE SANDOZ, 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 using PIRFENIDONE SANDOZ?

Things you should do

Call your doctor straight away if you:

- Experience nausea, headache or dizziness. Your doctor may monitor your sodium levels while you are taking PIRFENIDONE SANDOZ. PIRFENIDONE SANDOZ can cause low sodium levels in the blood.
- Become pregnant while taking this medicine.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PIRFENIDONE SANDOZ.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Keep all 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.

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

Things you should not do

- Do not stop using this medicine or lower the dosage without checking with your doctor. If you stop suddenly, your condition may worsen. If for any reason you have to stop taking PIRFENIDONE SANDOZ 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 PIRFENIDONE SANDOZ to treat any other complaints unless your doctor tells you to.
- Do not give your 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 PIRFENIDONE SANDOZ affects you.

PIRFENIDONE SANDOZ 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

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

Store it in a cool dry place below 30°C 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.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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>Skin related</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>Gut related</p> <ul style="list-style-type: none"> diarrhoea feeling sick (nausea) indigestion or stomach upset loss of appetite stomach problems such as acid reflux, vomiting, feeling bloated, abdominal pain and discomfort, heart burn, feeling constipated and passing wind. <p>Others</p> <ul style="list-style-type: none"> muscle aches or pain dizziness tiredness headache 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking PIRFENIDONE SANDOZ.</p>

Serious side effects

Serious side effects	What to do
<p>Mental states related</p> <ul style="list-style-type: none"> difficulty in sleeping feeling sleepy <p>Liver related:</p> <ul style="list-style-type: none"> yellowing of your skin or the white part of your eyes (jaundice) dark or brown (tea coloured) urine pain on the upper right side of your stomach area (abdomen) bleeding or bruising more easily than normal. <p>Allergy related</p> <ul style="list-style-type: none"> swelling of face, lips and/or tongue difficulty in breathing or wheezing <p>Infection related</p> <ul style="list-style-type: none"> infection of the throat or of the airways going into the lungs or sinusitis <p>Skin related</p> <ul style="list-style-type: none"> reddish non-elevated, or circular patches on the trunk, often with central blisters, skin peeling, 	<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>

<p>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, drug reaction with eosinophilia and systemic symptoms or toxic epidermal necrolysis.</p> <p>Others</p> <ul style="list-style-type: none"> • change in taste • weight loss 	
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PIRFENIDONE SANDOZ 801 mg – dark pink, oval, biconvex, film-coated tablets, debossed SD801 on one side.
(Aust R 356831)

Who distributes PIRFENIDONE SANDOZ

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

This leaflet was prepared in November 2023.

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.

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7. Product details

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

What PIRFENIDONE SANDOZ contains

Active ingredient (main ingredient)	pirfenidone
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • pregelatinised starch • croscarmellose sodium • hypollose • silicon dioxide • magnesium stearate • OPADRY II Complete Film Coating System Yellow (267 mg) • OPADRY II Complete Film Coating System Pink (801 mg)

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

What PIRFENIDONE SANDOZ looks like

PIRFENIDONE SANDOZ 267 mg – yellow, oval, biconvex, film-coated tablets, debossed SD267 on one side.
(Aust R 356830)