

Pirfenidone Dr.Reddy's

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 Dr.Reddy's?

Pirfenidone Dr.Reddy's contains the active ingredient Pirfenidone. Pirfenidone Dr.Reddy's is used to treat Idiopathic Pulmonary Fibrosis (IPF).

For more information, see Section [1. Why am I using Pirfenidone Dr.Reddy's?](#) in the full CMI.

2. What should I know before I use Pirfenidone Dr.Reddy's?

Do not use 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 Dr.Reddy's?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Pirfenidone Dr.Reddy's 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 Dr.Reddy's?

- Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use Pirfenidone Dr.Reddy's?](#) in the full CMI.

5. What should I know while using Pirfenidone Dr.Reddy's?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using pirfenidone.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine
Things you should not do	<ul style="list-style-type: none">• Do not this medicine to treat any other complaints unless your doctor tells you to. Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how medicine affects you.
Smoking	<ul style="list-style-type: none">• You should stop smoking before and during treatment with Pirfenidone Dr.Reddy's.• Cigarette smoking can reduce the effect of Pirfenidone Dr.Reddy's
Looking after your medicine	<ul style="list-style-type: none">• Keep your 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 your tablets in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Some common side effects include skin reactions after going out in the sun or using sunlamps or tanning beds, rash or itching, feeling sick (nausea) and tiredness.

There are also serious side effects such as infection of the throat or of the airways going into the lungs or/and sinusitis, weight loss, difficulty in sleeping, dizziness serious and 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.

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 Dr.Reddy's

Active ingredient(s): Pifenidone

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pirfenidone Dr.Reddy's. **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 Dr.Reddy's.**

Where to find information in this leaflet:

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

1. Why am I using Pirfenidone Dr.Reddy's?

Pirfenidone Dr.Reddy's contains the active ingredient pirfenidone.

Pirfenidone Dr.Reddy's 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.

Pirfenidone Dr.Reddy's 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.

This medicine is not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children.

2. What should I know before I use Pirfenidone Dr.Reddy's?

Warnings

Do not use Pirfenidone Dr.Reddy's 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 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.

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.

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

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

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.

Do not take Pirfenidone Dr.Reddy's if you are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder (OCD)).

Do not take Pirfenidone Dr.Reddy's if you have experienced an allergic reaction when previously taking Pirfenidone Dr.Reddy's.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take Pirfenidone Dr.Reddy's if you have or have had any of the following:

- severe liver problems
- severe kidney problems including dialysis

Do not take Pirfenidone Dr.Reddy's after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- are a smoker

Avoid the sun, including sunlamps or tanning beds, while taking Pirfenidone Dr.Reddy's.

You may become more sensitive to sunlight while taking Pirfenidone Dr.Reddy's.

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 Dr.Reddy's.

Cigarette smoking can reduce the effect of Pirfenidone Dr.Reddy's.

Pirfenidone Dr.Reddy's 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 Dr.Reddy's can cause weight loss.

Your doctor will monitor your weight while you are taking this medicine.

If you have not told your doctor about any of the above, tell him/ her before you start taking Pirfenidone Dr.Reddy's

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 Pirfenidone Dr.Reddy's 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 Pirfenidone Dr.Reddy's 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.

4. How do I use Pirfenidone Dr.Reddy's?

How much to take / use

- The recommended dose of Pirfenidone Dr.Reddy's is:
 - Days 1 to 7: one tablets, three times a day with food.
 - Days 8 to 14: two tablets, three times a day with food
 - Day 15 onward: three tablets, three times a day with food

How to take it

- Swallow the tablets whole with a full glass of water.
- Take Pirfenidone Dr.Reddy's with or immediately after food.

Follow the instructions provided and use Pirfenidone Dr.Reddy's until your doctor tells you to stop. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help

When to take / use Pirfenidone Dr.Reddy's

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 Pirfenidone Dr.Reddy's with or immediately after food.

It is important to take Pirfenidone Dr.Reddy's 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 Dr.Reddy's.

Grapefruit may prevent Pirfenidone Dr.Reddy's from working properly.

How long to take it

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 use Pirfenidone Dr.Reddy's

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 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 use too much Pirfenidone Dr.Reddy's

If you think that you have used too much Pirfenidone Dr.Reddy's, 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 Dr.Reddy's?

Things you should do

Call your doctor straight away if you:

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Pirfenidone Dr.Reddy's.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

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

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.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using Pirfenidone Dr.Reddy's.

Things you should not do

Do not take Pirfenidone Dr.Reddy's 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.

Do not stop taking your 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 Pirfenidone Dr.Reddy's for more than 14 consecutive days, your doctor will restart your treatment with 1 tablets 3 times a day, gradually increasing this to 3 tablets 3 times a day.

Things to be careful of Be careful driving or operating machinery until you know how Pirfenidone Dr.Reddy's affects you.

This medicine 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.

Pirfenidone Dr.Reddy's can cause low sodium level 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 Dr.Reddy's.

Looking after your medicine

- Keep your 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 your tablets in a cool dry place where the temperature stays below 30°C.
- Do not store Pirfenidone Dr.Reddy's or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.
- Heat and dampness can destroy some medicines.
- Keep it where children cannot reach it.
- A locked cupboard at least one-and-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
<ul style="list-style-type: none">• Skin reactions after going out in the sun or using sunlamps or tanning beds• rash or itching• feeling sick (nausea)• tiredness• diarrhoea• indigestion or stomach upset• loss of appetite• headache• muscle aches or pain• dizziness	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• infection of the throat or of the airways going into the lungs or/or sinusitis• stomach problems such as acid reflux, vomiting, feeling bloated, abdominal pain and discomfort, heart burn, feeling constipated and passing wind	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

<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. • changes in taste • weight loss • difficulty in sleeping • dizziness • feeling sleepy • swelling of face, lips and/or tongue, difficulty in breathing or wheezing. 	<p>these serious side effects.</p>
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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 Pirfenidone Dr.Reddy's contains

Active ingredient (main ingredient)	pirfenidone
Other ingredients (inactive ingredients)	Lactose monohydrate Croscarmellose sodium Colloidal silicon dioxide Povidone Purified water Magnesium stearate Polyvinyl alcohol Macrogol Titanium dioxide Purified talc Iron oxide black Iron oxide red Iron oxide yellow.
Potential allergens	lactose

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

What Pirfenidone Dr.Reddy's looks like

Pirfenidone Dr.Reddy's 267 mg film coated tablets are yellow, oval, film coated tablets, debossed with "S 35" on one side and plain on another side (Aust R 407541).

Pirfenidone Dr.Reddy's 801 mg film coated tablets are purple, oval, film coated tablets, debossed with "S 36" on one side and plain on another side (Aust R 407540).

Who distributes Pirfenidone Dr.Reddy's

Dr Reddy's Laboratories (Australia) Pty Ltd
Suite 3.03, Level 3, 390 St Kilda Road
Melbourne, VIC, 3004
Phone: 1800 733 397

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