

# ARX-Pirfenidone

## 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 -ARX-Pirfenidone?

ARX-Pirfenidone contain the active ingredient pirfenidone. ARX-Pirfenidone is used to treat Idiopathic Pulmonary Fibrosis (IPF).

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

### 2. What should I know before I use ARX-Pirfenidone?

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 ARX-Pirfenidone?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ARX-Pirfenidone 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 ARX-Pirfenidone?

- The recommended dose for adults is Days 1 to 7: one 267 mg tablet, three times a day with food; Days 8 to 14: two 267 mg tablets, three times a day with food and Day 15 onward: three 267 mg tablets or one 801 mg tablet, three times a day with food.
- Do not drink grapefruit juice while taking ARX-Pirfenidone.

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

### 5. What should I know while using ARX-Pirfenidone?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using ARX-Pirfenidone.</li><li>• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARX-Pirfenidone.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take ARX-Pirfenidone to treat any other complaints unless your doctor tells you to.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• ARX-Pirfenidone 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.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 30°C.</li><li>• Keep your tablets in the blister until it is time to take them.</li></ul>

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

### 6. Are there any side effects?

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, and dizziness are some of the side effects.

Serious side effects: yellowing of your skin or the white part of your eyes (jaundice), dark or brown urine, swelling or the face, lips or tongue with difficulty breathing, infection of the throat or of the airways going into the lungs or sinusitis, serious skin rashes with reddish non-elevated, or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. Tell your doctor as soon as possible if you notice any of these side effects or if you have weight loss, difficulty in sleeping, dizziness, feeling sleepy, changes in taste, or stomach problems.

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.

# ARX-Pirfenidone

Active ingredient: *pirfenidone*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-Pirfenidone. **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 ARX-Pirfenidone.**

**Where to find information in this leaflet:**

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

## 1. Why am I using ARX-Pirfenidone?

ARX-Pirfenidone contains the active ingredient pirfenidone.

ARX-Pirfenidone 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.

ARX-Pirfenidone 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.

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

## 2. What should I know before I use ARX-Pirfenidone?

### Warnings

**Do not take ARX-Pirfenidone if you have an allergy to:**

- any medicine containing pirfenidone
- any of the ingredients listed at the end of this leaflet.

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
- 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 ARX-Pirfenidone 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?](#)

**Do not take ARX-Pirfenidone if you are taking a medicine called fluvoxamine (used to treat depression and obsessive compulsive disorder (OCD)).**

**Do not take ARX-Pirfenidone if you have experienced an allergic reaction when previously taking ARX-Pirfenidone.**

**Do not take ARX-Pirfenidone if you have or have had any of the following:**

- severe liver problems
- severe kidney problems including dialysis

Do not take ARX-Pirfenidone 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 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?](#)

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

**Avoid the sun, including sunlamps or tanning beds, while taking ARX-Pirfenidone.**

**You may become more sensitive to sunlight while taking ARX-Pirfenidone.**

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 ARX-Pirfenidone.**

Cigarette smoking can reduce the effect of ARX-Pirfenidone.

### **ARX-Pirfenidone may cause dizziness and tiredness.**

Be careful if you have to take part in activities where you have to be alert and co-ordinated.

### **ARX-Pirfenidone 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 ARX-Pirfenidone.**

### **Pregnancy and breastfeeding**

**Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.**

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 ARX-Pirfenidone, your doctor will discuss the risks and benefits of taking this medicine while breast feeding.

### **Children and adolescents**

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.

### **ARX-Pirfenidone contains sodium**

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

## **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 ARX-Pirfenidone 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 ARX-Pirfenidone 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 ARX-Pirfenidone.**

## **4. How do I use ARX-Pirfenidone?**

**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 on the blister, ask your doctor or pharmacist for help.**

### **How much to use**

The recommended dose of ARX-Pirfenidone is: Days 1 to 7: one 267 mg tablet, three times a day with food

Days 8 to 14: two 267 mg tablets, three times a day with food

Day 15 onward: three 267 mg tablets or one 801 mg tablet, three times a day with food

### **How to use ARX-Pirfenidone**

Swallow the tablets whole with a full glass of water.

If you are having trouble swallowing the tablets talk to your pharmacist

Take ARX-Pirfenidone with or immediately after food.

### **When to use ARX-Pirfenidone**

**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 ARX-Pirfenidone with or immediately after food.**

It is important to take ARX-Pirfenidone 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 ARX-Pirfenidone.**

Grapefruit may prevent ARX-Pirfenidone 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 ARX-Pirfenidone**

**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 ARX-Pirfenidone**

If you think that you have used too much ARX-Pirfenidone, 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.

## **5. What should I know while using ARX-Pirfenidone?**

**Things you should do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARX-Pirfenidone.**

**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.

**Things you should not do**

**Do not take ARX-Pirfenidone 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 ARX-Pirfenidone 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.

**Things to be careful of**

ARX-pirfenidone 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 ARX-Pirfenidone.

**Driving or using machines**

**Be careful driving or operating machinery until you know how ARX-Pirfenidone 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.

**Looking after your medicine**

**Keep your tablets in the blister until it is time to take them.**

If you take the tablets out of the blister they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store ARX-Pirfenidone 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-a-half metres above the ground is a good place to store medicines.

### Getting rid of any unwanted 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.**

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.

## 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.

This medicine helps most people with IPF, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARX-Pirfenidone.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

### Less serious side effects

Less serious side effects	What to do
<b>Skin related:</b> <ul style="list-style-type: none"> <li>• skin reactions after going out in the sun or using sunlamps or tanning beds</li> <li>• rash or itching</li> </ul> <b>Stomach related:</b> <ul style="list-style-type: none"> <li>• feeling sick (nausea)</li> <li>• diarrhoea</li> </ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• indigestion or stomach upset</li> <li>• loss of appetite</li> </ul> <b>Other:</b> <ul style="list-style-type: none"> <li>• headache</li> <li>• muscle aches or pain</li> <li>• tiredness</li> </ul>	
--	--

### Serious side effects

Serious side effects	What to do
<b>Stomach related:</b> <ul style="list-style-type: none"> <li>• stomach problems such as acid reflux, vomiting, feeling bloated, abdominal pain and discomfort, heart burn, feeling constipated and passing wind</li> </ul> <b>Skin related:</b> <ul style="list-style-type: none"> <li>• 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, drug reaction with eosinophilia and systemic symptoms or toxic epidermal necrolysis.</li> </ul> <b>Other:</b> <ul style="list-style-type: none"> <li>• infection of the throat or of the airways going into the lungs or/ or sinusitis</li> <li>• weight loss</li> <li>• difficulty in sleeping</li> <li>• dizziness</li> <li>• feeling sleepy</li> <li>• changes in taste</li> </ul>	<b>Speak to your doctor as soon as possible if you have any of these side effects.</b>

### Very serious side effects

Very serious side effects	What to do
<b>Liver related:</b> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <b>Other:</b> <ul style="list-style-type: none"> <li>• swelling of face, lips and/or tongue, difficulty in breathing or wheezing.</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b>

**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](http://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.**

ARX-PIRFENIDONE pirfenidone 267 mg tablet blister pack  
AUST R 405524

ARX-PIRFENIDONE pirfenidone 801 mg tablet blister pack  
AUST R 405525

### Who distributes ARX-Pirfenidone

Arrotex Pharmaceuticals Pty Ltd  
15 – 17 Chapel Street,  
Cremorne, VIC 3121, Australia.

This leaflet was prepared in November 2024.

## 7. Product details

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

### What ARX-Pirfenidone contains

<b>Active ingredient (main ingredient)</b>	pirfenidone
<b>Other ingredients (inactive ingredients)</b>	Colloidal silicon dioxide, Hydroxy propylmethyl cellulose, Mannitol, Sodium starch glycolate, Sodium stearyl fumarate.
<b>Film coating</b>	Macrogol, Iron oxide red (801 mg), Iron oxide yellow (267 mg), Polyvinyl alcohol, Talc, Titanium dioxide

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

### What ARX-Pirfenidone looks like

ARX-Pirfenidone 267 mg film-coated tablets are light yellow to yellow, biconvex, oval shaped beveled edge, film-coated tablet, plain on both sides.

ARX-Pirfenidone 801 mg film-coated tablets are light pink to pink, biconvex, capsule shaped, film-coated tablet, plain on both sides.

ARX-Pirfenidone 267mg, and 801 mg film-coated tablets are available in a blister in carton containing 90 tablets.

### Australian Registration Number

