

# PULMORIS

## 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 Pulmoris?

Pulmoris contains the active ingredient ambrisentan. Pulmoris is used to treat adults with pulmonary arterial hypertension (PAH).

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

### 2. What should I know before I use Pulmoris?

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

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

Some medicines may interfere with Pulmoris 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 Pulmoris?

- The usual dose of Pulmoris is 5 mg, once a day

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

### 5. What should I know while using Pulmoris?

<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 Pulmoris.</li><li>• You must use reliable birth control (contraception) while using Pulmoris and for 3 months after you stop taking it. Use at least two reliable forms of birth control (contraception).</li><li>• If you are a male, you should avoid exposing your partner to your semen by use of appropriate contraception e.g. condoms.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate machines if you're feeling unwell.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Not applicable</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the pack until it is time to take them.</li><li>• Keep your tablets in a cool dry place where the temperature stays below 30°C.</li><li>• Do not store Pulmoris or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.</li></ul>

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

### 6. Are there any side effects?

Very common side effects: swelling especially in the ankles and feet, headache, a runny or blocked nose, congestion or pain in the sinuses, dizziness, fast or irregular heart beat, feeling tired, lack of energy, worsening shortness of breath shortly after starting Pulmoris, anaemia, when taking ambrisentan in combination with Tadalafil (another PAH) medicine. All the above apply plus: vomiting, redness of the skin, chest pain/discomfort, nausea, diarrhoea

Common side effects: constipation, pain in your stomach, feeling weak, vomiting, heart failure, hypotension, fainting, abnormal blood tests for liver function, runny nose, chest pain or discomfort, flushing, nose bleed, rash, ringing or buzzing in the ear in combination with Tadalafil, allergic reactions, visual disturbance.

Uncommon side effects include: signs that your liver may not be working as it normally should include: loss of appetite, sick, vomiting, fever, unusual tiredness, pain in the stomach, jaundice, your urine turns dark in colour, itching of the skin, abnormal liver function which may show up in your blood tests, sudden hearing loss, in combination with Tadalafil.

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.

# Pulmoris

Ambrisentan: (am" bri sen' tan)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Pulmoris. **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 Pulmoris.**

Where to find information in this leaflet:

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

## 1. Why am I using Pulmoris?

**Pulmoris contains the active ingredient ambrisentan.** Pulmoris is a type of medicine called an endothelin receptor antagonist (ERA).

**Pulmoris is used to treat adults with pulmonary arterial hypertension (PAH), which is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs.**

## 2. What should I know before I use Pulmoris?

### Warnings

**Do not use PULMORIS if:**

- you are allergic to ambrisentan, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- any other similar 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.
- you have scarring of the lungs of unknown cause (a condition known as idiopathic pulmonary fibrosis or IPF)
- you have or have had a serious liver problem
- you have raised levels of some liver enzymes (detected by blood tests).

**Check with your doctor if you:**

- have any other medical conditions
  - liver disease
  - heart disease called right heart failure
  - a low number of red blood cells (anaemia)
  - if you have swelling, especially of the ankles and feet (oedema)
  - low blood pressure
  - kidney problems.
- take any medicines for any other condition.
- have allergies to any other medicines, foods, preservatives or dyes.
- are breast-feeding or plan to breast feed.  
Your doctor can discuss with you the risks and benefits involved.

Your doctor will take blood tests to check:

- whether you have a reduced number of red blood cells (anaemia)
- that your liver is working properly.

These blood tests will be taken before you start taking Pulmoris and throughout your treatment with Pulmoris.

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.

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

**Do not take Pulmoris if you are pregnant or planning to become pregnant.**

It may affect your developing baby if you take it during pregnancy or if you become pregnant soon after you stop treatment.

**If it is possible you could become pregnant, you must use reliable birth control (contraception) while using Pulmoris and for 3 months after you stop taking it.**

**Use at least two reliable forms of birth control (contraception) while you are taking Pulmoris. Talk to your doctor about this.**

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you take Pulmoris.

If you are a male you should avoid exposing your partner to your semen by use of appropriate contraception e.g. condoms.

If you do become pregnant, talk to your doctor immediately.

## Children

- Pulmoris is not recommended for use in children as there have been no studies of its effects in children.

## Idiopathic Pulmonary fibrosis

- Pulmoris must not be used for the treatment of idiopathic pulmonary fibrosis (IPF) and must not be used in patients who have IPF with or without secondary pulmonary hypertension.

## 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.

- ciclosporin (a medicine taken if you have an organ transplant). If you take ciclosporin, do not take more than one 5 mg tablet of Pulmoris, once a day
- ketoconazole (medicine for fungal infection).

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

## 4. How do I use Pulmoris?

### How much to take / use

- The usual dose of Pulmoris is 5 mg, once a day. Your doctor may decide to increase your dose to 10 mg, once a day. If you take ciclosporin, do not take more than one 5 mg tablet of Pulmoris, once a day.
- Follow the instructions provided and use Pulmoris until your doctor tells you to stop.
- 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.

### When to take / use Pulmoris

- Pulmoris 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.
- It does not matter if you take this medicine before or after food.

### How to take Pulmoris

Swallow the tablet whole, with a glass of water.

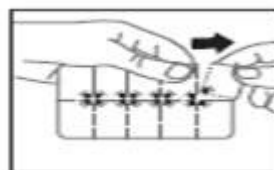
Pulmoris tablets should not be split, crushed or chewed.

You can take Pulmoris with or without food.

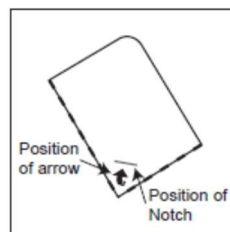
Pulmoris tablets are packaged in a special child resistant blister pack.

The diagrams below provide instructions on how best to remove the tablets from the packaging.

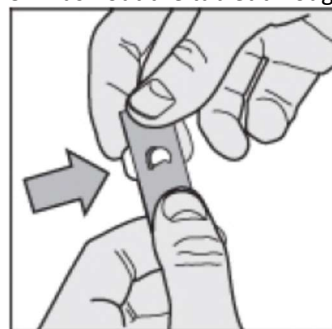
1. Tear along the perforated lines to separate one "pocket" from the blister strip.



2. Starting at the arrow corner, gently lift and peel back the outer layer over the pocket, exposing the foil beneath.



3. Push out the tablet through the exposed foil layer.



### If you forget to use Pulmoris

Pulmoris should be used regularly at the same time each day [week or month]. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**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 it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

### If you use too much Pulmoris

If you think that you have used too much Pulmoris, 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 Pulmoris?**

### **Things you should do**

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using Pulmoris.

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

**You must use reliable birth control (contraception) while using Pulmoris and for 3 months after you stop taking it. Use at least two reliable forms of birth control (contraception).**

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

**If you are a male, you should avoid exposing your partner to your semen by use of appropriate contraception e.g. condoms.**

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will need to take regular blood tests while you are taking this medicine to ensure your liver function and red blood cell (anaemia) levels remain normal.

### **Things you should not do**

- Do not stop using this medicine suddenly.
- Do not lower the dosage without checking with your doctor.
- Do not take Pulmoris 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 Pulmoris affects you.**

### **Looking after your medicine**

- Keep your tablets in the pack until it is time to take them.

- If you take the tablets out of the pack they may not keep well.
- Store below 30°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 (as relevant)**

Do not take this medicine 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.

### **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**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• swelling (oedema), especially in the ankles and feet</li><li>• headache</li><li>• a runny or blocked nose, congestion or pain in the sinuses</li><li>• dizziness</li><li>• palpitations (fast or irregular heart beat)</li><li>• feeling tired, lack of energy (fatigue)</li><li>• worsening shortness of breath shortly after starting Pulmoris</li><li>• signs of anaemia, such as tiredness, weakness, shortness of breath and feeling generally unwell</li><li>• when taking ambrisentan in combination with Tadalafil (another PAH) medicine. All the above apply plus:<ul style="list-style-type: none"><li>– vomiting</li><li>– flushing (redness of the skin)</li></ul></li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>– chest pain/discomfort</li> <li>– nausea</li> <li>– diarrhoea</li> </ul> <p>Common side effects</p> <ul style="list-style-type: none"> <li>• constipation</li> <li>• pain in your stomach</li> <li>• feeling weak</li> <li>• vomiting</li> <li>• heart failure</li> <li>• hypotension</li> <li>• fainting</li> <li>• abnormal blood tests for liver function</li> <li>• runny nose</li> <li>• chest pain or discomfort</li> <li>• flushing</li> <li>• nose bleed</li> <li>• rash</li> <li>• tinnitus (ringing or buzzing in the ear) when taking ambrisentan in combination with Tadalafil</li> <li>• allergic reactions: you may notice a rash or itching or swelling (usually of the face, lips or throat), which may cause difficulty in breathing or swallowing</li> <li>• visual disturbance (blurred vision or changes in your ability to see clearly).</li> </ul>	
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## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• signs that your liver may not be working as it normally should include: <ul style="list-style-type: none"> <li>– loss of appetite</li> <li>– sick (nausea)</li> <li>– vomiting</li> <li>– fever</li> <li>– unusual tiredness</li> <li>– pain in the stomach (abdominal pain)</li> <li>– yellow colouring of your skin or the whites of your eyes (jaundice)</li> <li>– your urine turns dark in colour</li> <li>– itching of the skin</li> <li>– abnormal liver function which may show up in your blood tests</li> </ul> </li> <li>• sudden hearing loss, in combination with Tadalafil.</li> </ul>	<p><b>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.</b></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](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.**

## 7. Product details

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

### What Pulmoris contains

<b>Active ingredient (main ingredient)</b>	Ambrisentan
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Microcrystalline cellulose,</li> <li>• Lactose monohydrate</li> <li>• Croscarmellose sodium,</li> <li>• Magnesium stearate.</li> </ul> <p>Tablet coating:</p> <ul style="list-style-type: none"> <li>• Pulmoris 5 mg contains Opadry II Complete Film Coating System 85G94065 Pink (ARTG PI No. 12699)</li> <li>• Pulmoris 10 mg contains Opadry II Complete Film Coating System 85G94101 Red (ARTG PI No. 12692)</li> </ul>
<b>Potential allergens</b>	NA

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

### What Pulmoris looks like

Pulmoris 5 mg is a pale pink, square shaped, biconvex, film-coated tablets debossed with "CL" on one side and "5" on the other side - AUST R 282338

Pulmoris 10 mg is a pink, oval shaped, biconvex, film-coated tablets debossed with "CL" on one side and "10" on the other side - AUST R 282337

### Who distributes Pulmoris

Arrotex Pharmaceuticals Pty Ltd  
15-17 Chapel St, Cremorne VIC 3121

This leaflet was prepared in October 2022.