

AMBRISENTAN VIATRIS

Consumer Medicine Information (CMI) summary

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

1. Why am I taking AMBRISENTAN VIATRIS?

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

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

2. What should I know before I take AMBRISENTAN VIATRIS?

Do not take if you have ever had an allergic reaction to ambrisentan, any other similar medicine 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.

AMBRISENTAN VIATRIS should not be used in children or adolescents under the age of 18 years.

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

3. What if I am taking other medicines?

Some medicines may interfere with AMBRISENTAN VIATRIS 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 AMBRISENTAN VIATRIS?

Follow dosage directions given to you by your doctor or pharmacist and continue taking it for as long as your doctor tells you.

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

5. What should I know while taking AMBRISENTAN VIATRIS?

Things you should do	- You must use reliable birth control (contraception) while taking AMBRISENTAN VIATRIS and for 3 months after you stop taking it. Use at least two reliable forms of birth control (contraception). - If you are a male, you should avoid exposing your partner to your semen by use of appropriate contraception e.g. condoms. - Call your doctor straight away if you become pregnant while taking this medicine. - Remind any doctor, dentist or pharmacist you visit that you are taking AMBRISENTAN VIATRIS.
Things you should not do	- Do not take AMBRISENTAN VIATRIS if you are pregnant or planning to become pregnant. - Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor.
Driving or using machines	- Be careful before you drive or use any machines or tools until you know how AMBRISENTAN VIATRIS affects you. - The symptoms of your condition can make you less fit to drive. - Do not drive or operate machines if you're feeling unwell.
Looking after your medicine	- Store below 25°C. - Store in original packaging.

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

6. Are there any side effects?

Side effects that have been reported include swelling, headache, a runny or blocked nose, congestion or pain in the sinuses, dizziness, palpitations, feeling tired, lack of energy, worsening shortness of breath shortly after starting, signs of anaemia, constipation, pain in your stomach, feeling weak, vomiting, heart failure, hypotension, fainting, abnormal blood tests for liver function, chest pain or discomfort, flushing, nose bleed, rash, allergic reactions, visual disturbance.

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.

AMBRISENTAN VIATRIS

Active ingredient(s): *ambrisentan*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking AMBRISENTAN VIATRIS?

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

AMBRISENTAN VIATRIS 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.**

In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to become tired, dizzy and short of breath. AMBRISENTAN VIATRIS works by widening the pulmonary arteries, making it easier for your heart to pump blood through them. This lowers the blood pressure and relieves your symptoms.

2. What should I know before I take AMBRISENTAN VIATRIS?

Warnings

Do not take AMBRISENTAN VIATRIS if:

- you are allergic to ambrisentan, any other similar medicine 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:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin

- you are pregnant or planning to become pregnant
- you have scarring of the lungs of unknown cause (a condition known as idiopathic pulmonary fibrosis or IPF)
- you have IPF with or without secondary pulmonary hypertension
- you have or have had a serious liver problem
- you have raised levels of some liver enzymes (detected by blood tests)
- the expiry date printed on the pack has passed 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.

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:
 - o liver disease
 - o heart disease called right heart failure
 - o a low number of red blood cells (anaemia)
 - o if you have swelling, especially of the ankles and feet (oedema)
 - o low blood pressure
 - o kidney problems

If any of these applies to you, your doctor will decide if AMBRISENTAN VIATRIS is suitable for you.

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 AMBRISENTAN VIATRIS 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 taking AMBRISENTAN VIATRIS and for 3 months after you stop taking it.

Use at least two reliable forms of birth control (contraception) while you are taking AMBRISENTAN VIATRIS. 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 AMBRISENTAN VIATRIS.

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.

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

Your doctor can discuss with you the risks and benefits involved.

Children

AMBRISANTAN VIATRIS is not recommended for use in children and patients under 18 years of age as there have been no studies of its effects in this age group.

Blood tests

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 AMBRISANTAN VIATRIS and throughout your treatment with AMBRISANTAN VIATRIS.

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 AMBRISANTAN VIATRIS and affect how it works. These include:

- cyclosporin A (a medicine taken if you have an organ transplant). If you take cyclosporin A, do not take more than one 5 mg tablet of AMBRISANTAN VIATRIS, 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 AMBRISANTAN VIATRIS.

4. How do I take AMBRISANTAN VIATRIS?

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.

How much to take

AMBRISANTAN VIATRIS

- the usual dose is 5 mg, once a day
- your doctor may decide to increase your dose to 10 mg, once a day

When take AMBRISANTAN VIATRIS

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

How long to take AMBRISANTAN VIATRIS

- 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.

How to take AMBRISANTAN VIATRIS

- Swallow the tablets whole, with a full glass of water.
- AMBRISANTAN VIATRIS tablets should not be split, crushed or chewed.
- You can take AMBRISANTAN VIATRIS with or without food.

If you forget to take AMBRISANTAN VIATRIS

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

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

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much AMBRISANTAN VIATRIS

If you think that you or anyone else has taken too much AMBRISANTAN VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) for advice, 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 AMBRISANTAN VIATRIS?

Things you should do

- You must use reliable birth control (contraception) while taking AMBRISANTAN VIATRIS and for 3 months after you stop taking it. Use at least two reliable forms of birth control (contraception).
- 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 and to prevent unwanted side effects.

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

Call your doctor straight away if you:

- Become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are taking AMBRISENTAN VIATRIS.

Things you should not do

- Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor.
- Do not take AMBRISENTAN VIATRIS 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.

Things to be careful of

- **If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how AMBRISENTAN VIATRIS affects you. The symptoms of your condition can make you less fit to drive.

Do not drive or operate machines if you're feeling unwell.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- store below 25°C
- store in original packaging

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

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.

Heat and dampness can destroy some medicines.

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

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 pulmonary arterial hypertension, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects

Your doctor will consider the risk of side effects when deciding which strength of AMBRISENTAN VIATRIS you should take.

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

Less serious side effects

Very common side effects (may affect more than one in ten people)	What to do
• swelling (oedema), especially in the ankles and feet • headache • a runny or blocked nose, congestion or pain in the sinuses • dizziness • palpitations (fast or irregular heartbeat) • feeling tired, lack of energy (fatigue) • worsening shortness of breath shortly after starting AMBRISENTAN VIATRIS • signs of anaemia, such as tiredness, weakness, shortness of breath and feeling generally unwell	Speak to your doctor if you have any of these less serious side effects and they worry you.

Common side effects (may affect up to 1 in 10 people)	What to do
• constipation • pain in your stomach • feeling weak • vomiting • heart failure • hypotension • fainting • abnormal blood tests for liver	Speak to your doctor if you have any of these common side effects and they worry you.

Common side effects (may affect up to 1 in 10 people)	What to do
• function • runny nose • chest pain or discomfort • flushing • nose bleed • rash • 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 • visual disturbance (blurred vision or changes in your ability to see clearly).	

Serious side effects

Serious side effects	What to do
signs that your liver may not be working as it normally should, including: • loss of appetite • sick (nausea) • vomiting • fever • unusual tiredness • pain in the stomach (abdominal pain) • yellow colouring of your skin or the whites of your eyes (jaundice) • your urine turns dark in colour • itching of the skin • abnormal liver function which may show up in your blood tests	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.

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 AMBRISENTAN VIATRIS contains

Active ingredient (main ingredient)	Ambrisentan 5 mg and 10 mg
Other ingredients (inactive ingredients)	• Microcrystalline cellulose • Lactose • Croscarmellose sodium • Magnesium stearate • OPADRY II complete film coating system 85F540046 PINK (ID:107526).
Potential allergens	Contains lactose

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

What AMBRISENTAN VIATRIS looks like

AMBRISENTAN VIATRIS is presented in packs of 30 tablets in two available strengths of 5 mg and 10 mg.

- **5 mg tablets:** are pink, filmcoated, round, biconvex tablets debossed with 'M' on one side of the tablet and 'AN' on the other side (AUST R 298940).
- **10 mg tablets:** are pink, filmcoated, capsule shaped, biconvex tablets debossed with 'M' on one side of the tablet and 'AN1' on the other side (AUST R 298941).

Who distributes AMBRISENTAN VIATRIS

Alphapharm Pty Ltd trading as Viatris/Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in September 2025.

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