

VOLIBRIS

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 VOLIBRIS?

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

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

2. What should I know before I use VOLIBRIS?

Do not use 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.

VOLIBRIS 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 use VOLIBRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VOLIBRIS 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 VOLIBRIS?

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 use VOLIBRIS?](#) in the full CMI.

5. What should I know while using VOLIBRIS?

Things you should do

- You must use reliable birth control (contraception) while using VOLIBRIS and for 3 months after you stop taking it. Use

	<p>at least two reliable forms of birth control (contraception)</p> <ul style="list-style-type: none"> ● 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 using VOLIBRIS
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take VOLIBRIS if you are pregnant or planning to become pregnant ● Do not stop using this medicine suddenly or lower the dosage without checking with your doctor
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful before you drive or use any machines or tools

	<p>until you know how VOLIBRIS affects you</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Store below 30°C • Store in original packaging

For more information, see Section [5. What should I know while using VOLIBRIS?](#) 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. When taking VOLIBRIS in combination with Tadalafil additional side effects that have been reported include nausea, diarrhoea and tinnitus.

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.

VOLIBRIS

Active ingredient: *ambrisentan*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using VOLIBRIS?

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

VOLIBRIS 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. VOLIBRIS widens 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 use VOLIBRIS?

Warnings

Do not use VOLIBRIS 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 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

- 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 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 or have had 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 including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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 VOLIBRIS 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 VOLIBRIS and for 3 months after you stop taking it.

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

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

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

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 VOLIBRIS and throughout your treatment with VOLIBRIS.

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 VOLIBRIS and affect how it works. These include:

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

4. How do I use VOLIBRIS?

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

VOLIBRIS

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

VOLIBRIS with Tadalafil

- when used in combination with Tadalafil (another PAH medicine), VOLIBRIS is usually started at 5 mg daily, and should be increased to 10 mg once a day, if you can tolerate a higher dose

If you take ciclosporin A, do not take more than one 5 mg tablet of VOLIBRIS, once a day.

When and how long to take VOLIBRIS

- 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.
- Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your

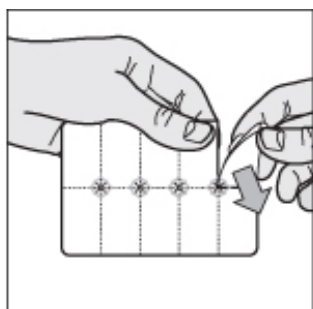
condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

How to take VOLIBRIS

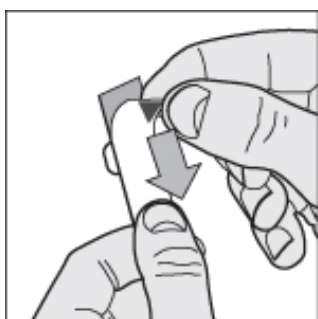
- swallow the tablet whole, with a glass of water
- VOLIBRIS tablets should not be split, crushed or chewed
- you can take VOLIBRIS with or without food

VOLIBRIS tablets are packaged in a special child resistant blister pack. The diagrams provide instructions on how best to remove the tablets from the packaging.

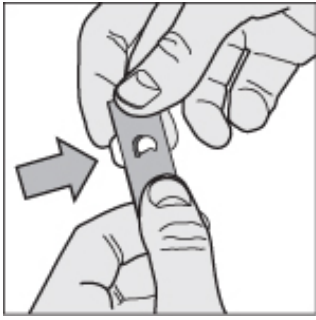
1. Tear along the perforated lines to separate one "pocket" from the blister strip



2. Starting at the coloured 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 VOLIBRIS

VOLIBRIS should be used regularly at the same time each day. 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 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 use too much VOLIBRIS

If you think that you have used too much VOLIBRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) in Australia, 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 VOLIBRIS?

Things you should do

You must use reliable birth control (contraception) while using VOLIBRIS 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.

Call your doctor straight away if you:

- become pregnant while taking this medicine.

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

Things you should not do

- do not stop using this medicine suddenly or lower the dosage without checking with your doctor

- do not take VOLIBRIS 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

Blood tests

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VOLIBRIS 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 30°C
- store in original packaging

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. 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 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.

Your doctor will consider the risk of side effects when deciding which strength of VOLIBRIS you should use.

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

Less serious side effects

Less serious side effects	What to do
<p>Vascular disorders</p> <ul style="list-style-type: none">• swelling (oedema), especially in the ankles and feet• hypotension• fainting <p>Nervous system disorders</p> <ul style="list-style-type: none">• headache• dizziness <p>Respiratory, thoracic and mediastinal disorders</p> <ul style="list-style-type: none">• a runny or blocked nose• nose bleed• congestion or pain in the sinuses <p>General disorders</p> <ul style="list-style-type: none">• feeling tired• lack of energy (fatigue)• feeling weak <p>Gastrointestinal disorders</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • constipation • pain in your stomach • vomiting <p>Hepatobiliary disorders</p> <ul style="list-style-type: none"> • abnormal blood tests for liver function <p>Skin and subcutaneous tissue disorders</p> <ul style="list-style-type: none"> • flushing <p>When taking VOLIBRIS in combination with Tadalafil (another PAH) medicine. All the above apply plus:</p> <ul style="list-style-type: none"> • vomiting • nausea • diarrhoea • chest pain/discomfort • tinnitus (ringing or buzzing in the ear) 	

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 707 589">Immune system disorders and allergic reactions</p> <ul data-bbox="204 629 754 965" style="list-style-type: none"><li data-bbox="204 629 754 965">● you may notice a rash or itching or swelling (usually of the face, lips or throat), which may cause difficulty in breathing or swallowing <p data-bbox="204 987 616 1032">Cardiac disorders</p> <ul data-bbox="204 1070 767 1312" style="list-style-type: none"><li data-bbox="204 1070 767 1178">● palpitations (fast or irregular heart beat)<li data-bbox="204 1193 504 1238">● heart failure<li data-bbox="204 1261 767 1312">● chest pain or discomfort <p data-bbox="204 1335 687 1491">Respiratory, thoracic and mediastinal disorders</p> <ul data-bbox="204 1536 707 1693" style="list-style-type: none"><li data-bbox="204 1536 707 1693">● worsening shortness of breath shortly after starting VOLIBRIS <p data-bbox="204 1715 523 1760">Eye disorders</p> <ul data-bbox="204 1805 783 2029" style="list-style-type: none"><li data-bbox="204 1805 783 2029">● visual disturbance (blurred vision or changes in your ability to see clearly)	<p data-bbox="810 432 1377 819">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>

Serious side effects	What to do
<p data-bbox="204 264 679 365">Blood and lymphatic system disorders</p> <ul style="list-style-type: none"> <li data-bbox="204 405 708 824">● signs of anaemia including: <ul style="list-style-type: none"> <li data-bbox="252 524 491 562">○ tiredness <li data-bbox="252 591 507 629">○ weakness <li data-bbox="252 658 708 696">○ shortness of breath <li data-bbox="252 725 647 824">○ feeling generally unwell <p data-bbox="204 864 743 913">Hepatobiliary disorders</p> <ul style="list-style-type: none"> <li data-bbox="204 954 740 1989">● signs that your liver may not be working as it normally should including: <ul style="list-style-type: none"> <li data-bbox="252 1189 619 1227">○ loss of appetite <li data-bbox="252 1256 580 1294">○ sick (nausea) <li data-bbox="252 1323 475 1361">○ vomiting <li data-bbox="252 1391 405 1429">○ fever <li data-bbox="252 1458 673 1496">○ unusual tiredness <li data-bbox="252 1525 715 1624">○ pain in the stomach (abdominal pain) <li data-bbox="252 1653 708 1863">○ yellow colouring of your skin or the whites of your eyes (jaundice) <li data-bbox="252 1892 740 1989">○ your urine turns dark in colour 	

Serious side effects	What to do
<ul style="list-style-type: none"> ○ itching of the skin ○ abnormal liver function which may show up in your blood tests <p>When taking VOLIBRIS in combination with Tadalafil (another PAH) medicine. All the above apply plus:</p> <ul style="list-style-type: none"> ● sudden hearing loss 	

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 VOLIBRIS contains

Active ingredient (main ingredient)	ambrisentan
Other ingredients (inactive ingredients)	microcrystalline cellulose lactose monohydrate croscarmellose sodium magnesium stearate polyvinyl alcohol purified talc titanium dioxide macrogol 3350 (PEG 3350) lecithin (Soya) USNF (E322) allura red AC aluminium lake (FD&C Red #40)
Potential allergens	Contains lactose

	VOLIBRIS contains the colouring agent allura red AC aluminium lake (FD&C Red #40), which may cause allergic-type reactions.
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Do not take this medicine if you are allergic to any of these ingredients.

What VOLIBRIS looks like

VOLIBRIS 5 mg tablets are a pale pink, square convex tablets engraved with 'GS' on one face and 'K2C' on the other.

VOLIBRIS 10 mg tablets are a deep pink, oval convex tablets engraved with 'GS' on one face and 'KE3' on the other.

VOLIBRIS 5 mg are available in packs of 30 tablets (AUST R 143743).

VOLIBRIS 10 mg are available in packs of 30 tablets (AUST R 143739).

Who distributes VOLIBRIS

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

This leaflet was prepared in May 2025.

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