

Volibris[®] 5 mg and 10 mg film coated tablets

Ambrisentan

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some common questions about VOLIBRIS.

VOLIBRIS has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What VOLIBRIS is used for

VOLIBRIS is a type of medicine called an endothelin receptor antagonist (ERA). It 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.

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

VOLIBRIS is available as 5 mg and 10 mg tablets.

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

Before you take VOLIBRIS

Do not take VOLIBRIS if:

- you are pregnant, are planning to become pregnant, or could get pregnant because you are not using reliable birth control (contraception)
- you have had an allergic reaction to VOLIBRIS or its ingredients
- you have or have had a serious liver problem
- you have raised levels of some liver enzymes (detected by blood tests).

Tell your doctor if the above applies to you.

Take special care with VOLIBRIS

Your doctor needs to know before you take VOLIBRIS if you have:

- liver disease
- a low number of red blood cells (anaemia)
- if you have swelling (oedema)
- low blood pressure.

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

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.

Signs that your liver may not be working as it normally should include: loss of appetite, feeling sick (nausea), being sick (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, or itching of the skin. If you notice any of these signs, tell your doctor immediately.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones – these include herbal medicines or other medicines you bought without a prescription.

Pregnancy and breast-feeding

Don't take VOLIBRIS if you or your partner are pregnant or planning to become pregnant as it may harm unborn babies conceived before, during or soon after treatment.

You must not become pregnant for at least 3 months after stopping VOLIBRIS.

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.

If it's possible you could become pregnant, use at least two reliable forms of birth control (contraception) while you're taking VOLIBRIS. Talk to your doctor about this.

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

Don't breast feed while you are taking VOLIBRIS.

Driving and using machines

It is not known whether VOLIBRIS affects your ability to drive or use machines. However, the symptoms of your condition can make you less fit to drive. Don't drive or operate machines if you're feeling unwell.

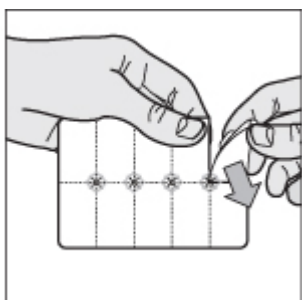
Ask your doctor or pharmacist for advice before taking any medicine if you are unsure.

How to take VOLIBRIS

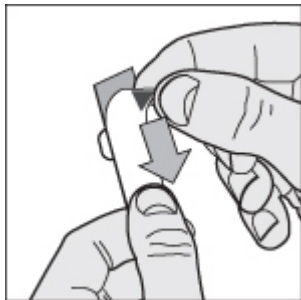
Always take VOLIBRIS exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

VOLIBRIS 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.

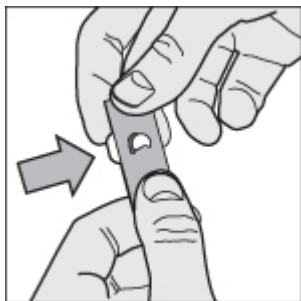
1. Tear along the perforated lines to separate one "pocket" from the blister strip.



2. Starting at the 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.



The usual dose of VOLIBRIS is 5 mg, once a day. Your doctor may decide to increase your dose to 10 mg, once a day.

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

It's best to take your tablet at the same time each day. Swallow the tablet whole, with a glass of water. You can take VOLIBRIS with or without food.

Once you have started taking VOLIBRIS

If you take too much VOLIBRIS

Immediately telephone your doctor or Poisons Information Centre (0800 POISON, 0800 764 766) or go to the accident and emergency department at your nearest hospital. Do this even if there are no signs of poisoning or discomfort. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

If you forget to take VOLIBRIS

If you forget to take a dose of VOLIBRIS, just take the tablet as soon as you remember, then carry on as before. Don't take two tablets at the same time to make up for a forgotten dose.

VOLIBRIS is a treatment that you will take long term. Don't stop taking VOLIBRIS without advice from your doctor.

Side effects

Like all medicines, VOLIBRIS can cause side effects. Your chances of getting these side effects will depend on many things, including how much VOLIBRIS you take.

Very common side effects (could affect more than one in 10 people) include:

- swelling (oedema), especially in the ankles and feet
- headache.

Other common side effects (could affect up to one in 10 people) include:

- low number of red blood cells (anaemia) which can cause tiredness, weakness, shortness of breath and feeling generally unwell. In some instances blood transfusions are required.
- rash or flushing (redness of the skin)
- a runny or blocked nose, congestion or pain in the sinuses
- constipation
- pain in your stomach
- nausea
- vomiting
- palpitations (fast or irregular heart beat).

If you notice any of the above side effects and any other unusual effects not listed in this leaflet while

taking VOLIBRIS, please tell your doctor or pharmacist.

Storage

Store below 30°C.

Keep out of the reach and sight of children.

Do not use VOLIBRIS after the expiry date which is stated on the carton.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description

What VOLIBRIS looks like

VOLIBRIS is presented in packs of 30 tablets.

VOLIBRIS is available in two strengths – 5 mg and 10 mg.

The 5 mg tablet is a pale pink, square convex tablet engraved with 'GS' on one face and 'K2C' on the other.

The 10 mg tablet is a deep pink, oval convex tablet engraved with 'GS' on one face and 'KE3' on the other.

Ingredients

VOLIBRIS contains the active ingredient ambrisentan.

VOLIBRIS also contains Microcrystalline Cellulose, Lactose, 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)

Distributor

VOLIBRIS is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067
Australia

VOLIBRIS is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information:

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

This leaflet was prepared on 10 October 2011.

The information provided applies only to: VOLIBRIS®.

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VOLIBRIS®:
5 mg – AUST R 143743
10 mg - AUST R 143739

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