

VOLIBRIS FILM COATED TABLET

Ambrisentan (5 mg, 10 mg)

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What Volibris is used for

It is used to treat pulmonary arterial hypertension (PAH) in adults. PAH 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 feel tired, dizzy and short of breath.

How Volibris works

Volibris contains the active substance ambrisentan. It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure). Volibris widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

Volibris may also be used in combination with other medicines used to treat PAH.

Before you use Volibris

- When you must not use it

Do not take Volibris:

- if you are allergic to ambrisentan, soya, or any of the other ingredients of this medicine. Volibris tablets contain lecithin derived from soya. If you are allergic to soya, do not use this medicine.
- if you are pregnant, if you are planning to become pregnant, or if

you could become pregnant because you are not using reliable birth control (contraception)

- if you are breast feeding
- if you have liver disease. Talk to your doctor, who will decide whether this medicine is suitable for you
- if you have scarring of the lungs, of unknown cause (idiopathic pulmonary fibrosis)

Volibris is not recommended for children and adolescents aged under 18 years as the safety and effectiveness is not known in this age group.

- Before you start to use it

Talk to your doctor before taking this medicine if you have:

- liver problems
- anaemia (a reduced number of red blood cells)
- swelling in the hands, ankles or feet caused by fluid (*peripheral oedema*)
- lung disease where the veins in the lungs are blocked (*pulmonary veno-occlusive disease*)

Your doctor will decide whether Volibris is suitable for you.

Volibris tablets contain small amounts of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Volibris.

You will need regular blood tests

Before you start taking Volibris, and at regular intervals while you are taking it, your doctor will take blood tests to check:

- whether you have anaemia
- whether your liver is working properly

It is important that you have these regular blood tests for as long as you are taking Volibris.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to adjust your dose of Volibris if you start taking:

- cyclosporine A (a medicine used after transplant or to treat psoriasis).
- rifampicin (an antibiotic used to treat serious infections) your doctor will monitor you when you first start taking Volibris.
- other medicines used to treat PAH (e.g. iloprost, epoprostenol, sildenafil) your doctor may need to monitor you.

Tell your doctor or pharmacist if you are taking any of these medicines.

How to use Volibris

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

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

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

- When to use it

It is best to take your tablet at the same time each day. Swallow the tablet whole, with a glass of water, do not chew or break the tablet. You can take Volibris with or without food.

- How long to use it

Volibris is a treatment that you will need to keep on taking to control your PAH. Do not stop taking Volibris unless you have agreed this with your doctor.

- If you forget to use it

If you forget to take a dose of Volibris, just take the tablet as soon as you remember, then carry on as before. Do not take two doses at the same time to make up for a forgotten dose.

- If you use too much (overdose)

If you take too many tablets you may be more likely to have side effects, such as headache, flushing, dizziness, nausea (feeling sick), or low blood pressure that could cause light-headedness. Ask your doctor or pharmacist for advice if you take more tablets than prescribed.

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Volibris may harm unborn babies conceived before, during or soon after treatment. If it is possible you could become pregnant, use a reliable form of birth control (contraception) while you are taking Volibris. Talk to your doctor about this.

If you become pregnant or think that you may be pregnant while you are taking Volibris, see your doctor immediately.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking Volibris and regularly while you are taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

Do not stop taking Volibris without your doctor's advice.

Do not take Volibris if you are

pregnant or planning to become pregnant.

It is not known if Volibris is transferred to breast milk. Do not breast-feed while you are taking Volibris. Talk to your doctor about this.

This medicine 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.

- Things to be careful of

If you are a man taking Volibris, it is possible that this medicine may lower your sperm count. Talk to your doctor if you have any questions or concerns about this.

Volibris may cause side effects, such as low blood pressure, dizziness, tiredness, that may affect your ability to drive or use machines. The symptoms of your condition can also make you less fit to drive or use machines.

Do not drive or use machines if you are feeling unwell.

Volibris tablets contain a colouring called Allura red AC Aluminium Lake (E129) which can cause allergic reactions.

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

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you and your doctor need to look out for:

Allergic reactions

This is a common side effect that may affect up to one in 10 people. You may notice a rash or itching and swelling (usually of the face, lips, tongue or throat), which may cause difficulty in breathing or swallowing.

Swelling (oedema), especially of the ankles and feet

This is a very common side effect that may affect more than one in 10 people.

Heart failure

This is due to the heart not pumping out enough blood, causing shortness of breath, extreme tiredness and swelling in the ankles and legs. This is a common side effect that may affect up to one in 10 people.

Anaemia (reduced number of red blood cells)

This is a blood disorder which can cause tiredness, weakness, shortness of breath, and generally feeling unwell. Sometimes this requires a blood transfusion. This is a very common side effect that may affect more than one in 10 people.

Hypotension (low blood pressure)

This can cause light-headedness. This is a common side effect that may affect up to one in 10 people. Tell your doctor straight away if you get these effects or if they happen suddenly after taking Volibris.

It is important to have regular blood tests, to check for anaemia and that your liver is working properly.

Other side effects

Very common side effects:

- headache
- dizziness
- palpitations (fast or irregular heart beats)
- worsening shortness of breath shortly after starting Volibris
- a runny or blocked nose, congestion or pain in the sinuses
- feeling sick (nausea)
- diarrhoea
- feeling tired

In combination with tadalafil (another PAH medicine)

In addition to the above:

- flushing (redness of the skin)
- being sick (vomiting)
- chest pain/discomfort

Common side effects:

- blurry or other changes to vision
- fainting
- abnormal blood test results for liver function
- a runny nose
- constipation
- pain in your stomach (abdomen)
- chest pain or discomfort
- flushing (redness of the skin)
- being sick (vomiting)
- feeling weak
- nose bleed
- rash

In combination with tadalafil

In addition to the above, except abnormal blood test results for liver function:

- ringing in the ears (tinnitus) only when taking the combination treatment.

Uncommon side effects:

- liver injury
- inflammation of the liver caused by the body's own defences (*autoimmune hepatitis*)

In combination with tadalafil

- sudden hearing loss

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed on this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Volibris

- Storage

Keep this medicine out of the sight and reach of children
Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.

The expiry date refers to the last day of that month.

Store below 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

5 mg film-coated tablets

Pale-pink, square, convex, film-coated tablet with "GS" debossed on one side and "K2C" on the other side.

10 mg film-coated tablets

Deep-pink, oval, convex, film-coated tablet with "GS" debossed on one side and "KE3" on the other side.

The tablets are available in PVC/PVDC/aluminium foil blisters. Pack sizes of 10 or 30 film-coated tablets. Not all pack sizes may be marketed.

- Ingredients

- Active ingredient(s)

5 mg or 10 mg of ambrisentan

- Inactive ingredient(s)

Tablet core

Lactose monohydrate
Microcrystalline cellulose
Croscarmellose sodium
Magnesium stearate

Film coat

Polyvinyl alcohol (partially hydrolyzed)
Talc (E553b)
Titanium dioxide (E171)
Macrogol 3350
Lecithin (Soya) (E322)
Allura red AC Aluminium Lake (E129)

- MAL number

Volibris 5 mg Film Coated Tablet
MAL20102008ACRZ

Volibris 10 mg Film Coated Tablet
MAL20102009ACRZ

Manufacturer

Patheon Inc.
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Product Registration Holder

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