PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VOLMARO 5 Film-coated Tablets

VOLMARO 10 Film-coated Tablets

Ambrisentan

Contains Sugar (Lactose Monohydrate 95 mg and 90 mg lactose per 5 mg and 10 mg tablet, respectively)

Read all of this leaflet carefully because before you start taking VOLMARO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse, or other health care provider.
- VOLMARO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VOLMARO is and what it is used for.
2. What you need to know before you take VOLMARO.
3. How to take VOLMARO.
4. Possible side effects
5. How to store VOLMARO
6. Contents of the pack and other information.

1. What VOLMARO is and what it is used for

VOLMARO contains the active substance ambrisentan.

It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure).

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 must work harder to pump blood through them. This causes people to feel tired, dizzy, and short of breath.

VOLMARO widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

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

2. What you need to know before you take VOLMARO

Do not take VOLMARO if:

- you are allergic to ambrisentan, soya, or any of the other ingredients of this medicine (as listed in **section 6**)
- 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). Please read the information under ‘Pregnancy’
- you are breast feeding. Read the information under ‘Breast-feeding’
- 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).

Warnings and precautions

Tell your doctor or health care provider before taking VOLMARO if**:**

- you have liver problems
- you have anaemia (a reduced number of red blood cells)
- you have swelling in the hands, ankles or feet caused by fluid (peripheral oedema)
- you have lung disease where the veins in the lungs are blocked (pulmonary veno-occlusive disease).
- you have been told by your doctor that you have an intolerance to some sugars,

Your doctor will decide whether VOLMARO is suitable for you.

You will need regular blood tests

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

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

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

Signs that your liver may not be working properly include:

- loss of appetite
- feeling sick (nausea)
- being sick (vomiting)
- high temperature (fever)
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine

- itching of your skin.

If you notice any of these signs, Tell your doctor immediately.

Children and adolescents

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

Other medicines and VOLMARO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Your doctor may need to adjust your dose of VOLMARO if you start taking cyclosporine A (a medicine used after transplant or to treat psoriasis).

If you are taking rifampicin (an antibiotic used to treat serious infections) your doctor will monitor, you when you first start taking VOLMARO.

If you are taking 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.

Pregnancy, breastfeeding, and fertility

Pregnancy

- VOLMARO 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 VOLMARO. Talk to your doctor about this.
- Do not take VOLMARO if you are pregnant or planning to become pregnant.
  If you become pregnant or think that you may be pregnant while you are taking VOLMARO, 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 VOLMARO and regularly while you are taking this medicine.

Breastfeeding

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

Fertility

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

Driving and using machines

VOLMARO may cause side effects, such as low blood pressure, dizziness, tiredness (see **section 4**), 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.

VOLMARO contains sugar in the form of Lactose monohydrate, lecithin (soya) (E322), Allura red AC Aluminium Lake (E129)

- VOLMARO tablets contain sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars: Contact your doctor before taking VOLMARO.
- VOLMARO tablets contain lecithin derived from soya. If you are allergic to soya, do not use this medicine (see **section 2** ‘Do not take VOLMARO’).

- VOLMARO tablets contain a colouring called Allura red AC Aluminium Lake (E129) which can cause allergic reactions (see **section 4**).

3. How to take VOLMARO

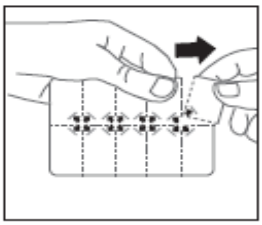
Do not share medicines prescribed for you with any other person.

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

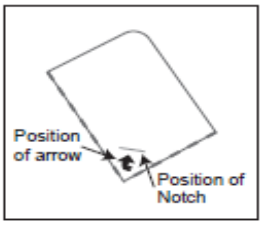
The usual dose of VOLMARO is one 5 mg tablet, once a day.
Your doctor may decide to increase your dose to 10 mg, once a day.
If you take cyclosporine A, do not take more than one 5 mg tablet of VOLMARO, once a day.
Your doctor will tell you how long your treatment with VOLMARO will last. Do not stop treatment early because you feel better. if you have the impression that the effect of VOLMARO is too strong or too weak, tell your doctor or pharmacist.
It is best to take your tablet at the same time each day.
Take tablet with sufficient quantity of water
Swallow tablet whole, with a glass of water, do not split, crush, or chew the tablet
You can take VOLMARO with or without food.

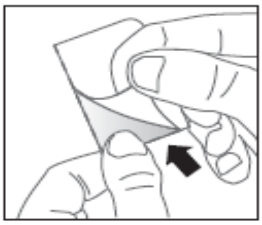
Instructions on how to remove tablet from the pack

These tablets come in special packaging to prevent children removing them.

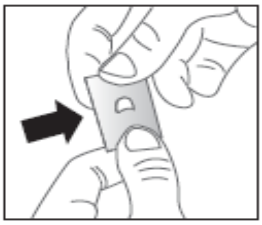


1. **Separate one pocket:** tear along the cutting lines to separate one “pocket” from the Blister.





2. **Peel back the outer layer:** Lift the outer layer from the arrow corner towards the notch to loosen the outer layer and further peel off the outer layer completely.



3. **Push out the tablet:** gently push the tablet from the pocket side so that the tablet comes out of the foil layer.

If you take more VOLMARO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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.

If you forget to take VOLMARO

If you forget a dose of VOLMARO, 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 individual dose.

If you stop taking VOLMARO

VOLMARO is a treatment that you will need to keep on taking to control your PAH.

Do not stop taking VOLMARO unless you have agreed this with your doctor.

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

4. Possible side effects

VOLMARO can have side effects.

Not all side effects reported for VOLMARO are included in this leaflet. Should your general health worsens or if you experience any untoward effects while taking VOLMARO, please consult your health care provider for advice.

If any of the following happens, stop taking VOLMARO and tell your doctor immediately or go to the casualty department at your nearest hospital:

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 VOLMARO

It is important to have regular blood tests, to check for anaemia and that your liver is working properly. **Make sure that you have also read the information in section 2** under 'You will need regular blood tests' and 'Signs that your liver may not be working properly'.

Tell your doctor if you notice any of the following:

Other side effects include

Frequent side effects:

- headache
- dizziness

- palpitations (fast or irregular heartbeats)
- worsening shortness of breath shortly after starting VOLMARO
- a runny or blocked nose, congestion, or pain in the sinuses
- feeling sick (nausea)
- diarrhoea
- feeling tired.

Less frequent 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
- nosebleed
- rash.

Side effects of which Frequency is unknown:

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

These are all serious side effects. You may need urgent medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of VOLMARO.

5. How to store VOLMARO

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package / container.

Do not use after the expiry date stated on the label

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VOLMARO contains

The active substance is: Ambrisentan.

The other ingredients are:

Croscarmellose sodium (Ac-Di-Sol),

lactose monohydrate (Lactopress granulated),

magnesium stearate (Vegetable grade),

microcrystalline cellulose (Avicel PH 102),

Opadry II complete film coating system: 85G94065 Pink/ 85G94101 Red:

polyvinyl alcohol (E1203),

Talc (E553b),

Titanium dioxide (E171),

Macrogol / PEG 4000 (E1521),

Lecithin (Soya) (E322),

Allura red AC Aluminium Lake (E129).

What VOLMARO looks like and contents of the pack

VOLMARO 5

Pale pink, square shaped, biconvex film coated tablets debossed with ‘CL’ on one side and ‘5’ on other side.

It is packed in Blister pack of 10`s and 3 x 10`s film coated tablets packed in a 270 gsm CFB board type 4 plain carton. The blister pack is composed of Lidding Peel – Push Aluminium Foil 206 mm, 50 gsm paper and 0.25 / 206 mm PVC / 60 gsm PVDC coated white opaque film.

VOLMARO 10

Deep pink oval shaped biconvex film coated tablets, debossed with 'CL' on one side and '10' on other side.

It is packed in Blister pack of 10`s and 3 x 10`s film coated tablets packed in a 270 gsm CFB board type 4 plain carton. The blister pack is composed of Lidding Peel – Push Aluminium Foil 206 mm, 50 gsm paper and 0.25 / 206 mm PVC / 60 gsm PVDC coated white opaque film.

Holder of Certificate of Registration

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