VOLIBRIS

Patient Information Leaflet

SCHEDULING STATUS:

S4

VOLIBRIS 5 mg film-coated tablets

VOLIBRIS10 mg film-coated tablets

Ambrisentan

Contains sugar:

VOLIBRIS 5 mg: Each tablet contains 95 mg lactose monohydrate.

VOLIBRIS 10 mg: Each tablet contains 90 mg lactose monohydrate.

Read all of this leaflet carefully before you are administered VOLIBRIS:

- 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.
- VOLIBRIS 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 VOLIBRIS is and what it is used for

2. What you need to know before you take VOLIBRIS

3. How to use VOLIBRIS

4. Possible side effects

5. How to store VOLIBRIS

6. Contents of the pack and other information

1. What VOLIBRIS is and what it is used for:

VOLIBRIS contains the active substance ambrisentan. It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure).

VOLIBRIS is used to treat pulmonary arterial hypertension (PAH). 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.

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

VOLIBRIS has not been studied in patients under 18 years old.

2. What you need to know before you take VOLIBRIS:

Do not take VOLIBRIS if:

- if you are hypersensitive (allergic) to ambrisentan or any of the inactive other ingredients of VOLIBRIS (listed in section 6)
- if you have severe liver problems
- if you have scarring of the lungs, of unknown cause (idiopathic pulmonary fibrosis)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions:

Talk to your doctor before taking VOLIBRIS:

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

Tell your doctor, who will decide whether VOLIBRIS is suitable for you.

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 to check:

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

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

Children and adolescents:

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

Other medicine and VOLIBRIS

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

Your doctor may need to adjust your dose of VOLIBRIS if you start taking ciclosporin A (a medicine used after transplant or to treat psoriasis). Tell your doctor or pharmacist if you are taking this medicine.

Taking VOLIBRIS with food and drink:

You can take VOLIBRIS with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking VOLIBRIS.

Pregnancy: 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're taking VOLIBRIS. Talk to your doctor about this.

Don't take VOLIBRIS if you are pregnant or planning to become pregnant. If you become pregnant or think that you may be pregnant while you're taking VOLIBRIS, see your doctor immediately.

Do not take VOLIBRIS 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 this applies to you, tell you doctor and do not take VOLIBRIS.

Breastfeeding: It is not known if VOLIBRIS is transferred to breast milk. Don't breastfeed while you are taking VOLIBRIS. Talk to your doctor about this.

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

Driving and using machines:

VOLIBRIS is unlikely to produce an effect on the ability to drive and use machines.

However, do not drive or operate machines if you are feeling unwell.

VOLIBRIS contains lactose:

VOLIBRIS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take VOLIBRIS.

VOLIBRIS contains lecithin (soya):

VOLIBRIS tablets contain lecithin, derived from soya. If you are allergic to soya, do not use VOLIBRIS.

VOLIBRIS contains Allura red AC Aluminium Lake:

VOLIBRIS tablets contain Allura red AC Aluminium Lake, which is a colourant, which may cause allergic reactions.

3. How to take VOLIBRIS:

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

Always take VOLIBRIS exactly as your doctor 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 ciclosporin A, do not take more than one 5 mg tablet of VOLIBRIS, once a day.

If you take VOLIBRIS with another medicine called tadalafil, the usual dose is 10 mg once a day.

It is best to take your tablet at the same time each day.

You can take VOLIBRIS with or without food.

If you have the impression that the effect of VOLIBRIS is too strong or too weak, tell your doctor.

If you take more VOLIBRIS than you should:

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

If you forget to take VOLIBRIS:

If you forget 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 stop taking VOLIBRIS:

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

4. Possible side effects:

VOLIBRIS can have side effects. Not all side effects reported for VOLIBRIS are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking VOLIBRIS, please consult your doctor, pharmacist or other health care provider for advice.

Liver function: VOLIBRIS may affect the levels of your liver enzymes which may cause damage to your liver. Your doctor will be doing regular blood tests to ensure that this does not happen. 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, yellowing of your skin or the whites of your eyes (jaundice), dark-coloured urine and itching of your skin. If you notice any of these signs, tell your doctor immediately.

Anaemia (a reduced number of red blood cells): Anaemia can cause tiredness, weakness, shortness of breath and generally feeling unwell. Your doctor will be doing regular blood tests to ensure that this does not happen. If you notice any of these signs, tell your doctor immediately. In some instances, a blood transfusion may be required.

- palpitations (fast or irregular heartbeats)
- worsening shortness of breath shortly after starting VOLIBRIS

Allergic reactions: 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.

- Tell your doctor straight away if you get these effects, or if they happen suddenly after taking VOLIBRIS:

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- swelling (oedema), especially of the ankles and feet
- headache
- anaemia (see above)
- a runny or blocked nose, red and sore throat, congestion of pain in the sinuses
- constipation
- pain in your stomach (abdomen)
- feeling sick (nausea)
- feeling tired, lack of energy (fatigue)
- flushing (redness of the skin)
- palpitations (fast or irregular heartbeats)
- dizziness
- worsening shortness of breath shortly after starting VOLIBRIS
- vomiting when taking VOLIBRIS in combination with tadalafil (another PAH medicine)
- feeling weak
- constipation
- vomiting
- visual impairment (blurry or other changes to vision)
- allergic reactions (see above)
- ringing in ears (tinnitus) when taking VOLIBRIS in combination with tadalafil (another PAH medicine).

Tell your doctor straight away if you get these effects or if they happen suddenly after taking VOLIBRIS.

The frequency of the following side effect is not known:

- anaemia that requires blood transfusion
- heart failure (associated with swelling/oedema)
- low blood pressure.
- liver injury
- inflammation of the liver caused by the body's own defences (auto-immune hepatitis).

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 pharmacist. 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. By reporting side effects, you can help provide more information on the safety of VOLIBRIS.

5. How to store VOLIBRIS:

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use VOLIBRIS after the expiry date shown on the pack.

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What VOLIBRIS contains:

Each tablet contains 5 mg or 10 mg ambrisentan.

The inactive ingredients are: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, polyvinyl alcohol, talc, titanium dioxide (E171), macrogol/polyethylene glycol 3350, lecithin (soya) and Allura Red AC Aluminium Lake (E129)

What VOLIBRIS looks like and contents of the pack:

VOLIBRIS 5 mg: Pale pink, square, convex film-coated tablet debossed with 'GS' on one side and 'K2C' on the other side.

VOLIBRIS 10 mg: Deep pink, oval, convex film-coated tablet debossed with 'GS' on one side and 'KE3' on the other side.

VOLIBRIS tablets are packed into opaque PVC/PVdC and aluminium foil blister strips containing 10 tablets each. Three blister strips are packed into a carton giving a 30 tablet pack.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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