

Information for patients who have been prescribed Volibris.

Taking Volibris (ambrisentan)
—what you need to know

This booklet gives you information and advice about taking Volibris, which is also known as ambrisentan.

Read it carefully.

Keep this booklet with you while you are taking Volibris. If you see a doctor who is not your usual healthcare provider, show them this card.

The Patient Information Leaflet inside each pack of Volibris tablets gives you more detailed information. Please read that too.

If there's anything here that you don't understand, or if you have any more questions, talk to your doctor, specialist nurse or pharmacist.

PLEASE TAKE THIS BOOKLET WITH YOU TO ALL YOUR APPOINTMENTS

Patient information

Name

Address

Telephone number

Treating Physician

Treating Physician's address

Treating Physician's telephone

Your PAH specialist information

This section should be completed by the prescribing doctor

Hospital

Consultant

Pulmonary nurse

Department

Clinic

Hospital Address

Telephone (appointments)

Telephone (information)

Telephone (emergency)

Telephone (hospital pharmacy)

What is PAH? What is Volibris and how does it work?

You have been prescribed Volibris to treat your *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. When people have PAH, these arteries become narrower—so the heart has to work harder to pump blood through them. People with PAH often feel tired, dizzy and short of breath, especially when they exercise.

Volibris is a type of medicine called an endothelin receptor antagonist (ERA). It works by making the pulmonary arteries wider, so the heart can more easily pump blood through them. This lowers the blood pressure, and relieves the symptoms. Volibris works in the majority of patients but may not work in everyone. It is important to let your doctor know whether the medication is working for you.

If you require further information about PAH, please speak to your doctor or nurse.

Who can't take Volibris?

Some people must not take Volibris.

Don't take it:

- If you are pregnant or planning to become pregnant
- If you are a woman who could become pregnant and you are not using reliable birth control (contraception)
- If you are breast feeding
- If you have severe liver disease
- If you are under 18 years old
- If you have ever had an allergic reaction to this medicine
- If you are allergic (*hypersensitive*) to soya.
- If you have **scarring of the lungs** of unknown cause (idiopathic pulmonary fibrosis)

Speak to your doctor:

- If you have kidney disease
- If you have anaemia (a low red blood cell count)

How to take Volibris

- **Take Volibris once each day.** You can take it any time, but it's best to take it at the same time every day. You can take it with or without food, it is recommended not to split, crush or chew the tablet.
- **If you miss a dose,** take it as soon as you remember, then carry on taking it as before, at your usual time. But if it's nearly time for your next dose, skip the missed dose.
- **Never take two doses at the same time** to make up for a missed dose. If you do, you could have side effects such as dizziness and fainting, if your blood pressure becomes too low.
- **Don't take any more Volibris than your doctor has advised you to.**
- **Don't stop taking Volibris** unless you have agreed this with your doctor.
- **Don't give Volibris to anyone else,** even if their symptoms seem to be the same as yours.

While you are taking Volibris, remember:

You will need regular blood tests:

- To check how well your liver is working. These tests are recommended every month.
- To check whether you are anaemic (have a low red blood cell count). These tests are recommended after 1 and 3 months of treatment, and from time to time after that. Your doctor will make sure these happen when needed.

If you see any other doctor:

If you see a doctor who is not your usual healthcare provider, it is important to tell them you are taking Volibris.

Carry this booklet with you, in case of emergency.

Pregnancy and Volibris

If you are a woman who could become pregnant:

Volibris may potentially harm or even cause birth defects in babies conceived before, during, or up to a month after treatment.

- **If you are pregnant**, you won't be able to start taking Volibris.
- Your doctor will ask you to take a **pregnancy test** before you start taking Volibris, and at regular intervals (e.g. monthly) while you are taking it.
- **It is very important for you to use a reliable form of contraception** (birth control) while you are taking Volibris. It's preferable that you and your partner use two methods of contraception that work in a different way e.g. double barrier method plus one other. Discuss this with your doctor.
- **If you miss a period**, or think you might be pregnant, contact your doctor straight away.
- **If you do become pregnant**, talk to your doctor as soon as possible about the risks and benefits of continuing to take Volibris.

- If you are considering whether to plan a pregnancy, talk to your doctor about it.
- **If you stop taking Volibris**, you must not become pregnant for at least one month afterwards.
- **If you need to change or stop** the contraception you are using:
 - **tell the doctor** who prescribes your contraception that you are taking Volibris
 - **tell the doctor** who prescribes Volibris about the change to your contraception.

Remember to take this booklet with you to all appointments

If you are a man taking Volibris:

It is possible that Volibris could lower your sperm count, which would affect your ability to father children.

- Talk to your doctor if you have any questions or concerns about this.
- If you are particularly concerned you may want to consider storing a sperm sample prior to starting treatment.

Possible side effects of Volibris

The Patient Information Leaflet in each pack of tablets has a full list of the known side effects of Volibris.

Be aware of signs that you might have the following side effects:

Swelling (*oedema*), especially of the ankles and feet

What to do: Tell your doctor if you notice this side effect, or if you find that it is getting worse.

Anaemia (a reduced number of red blood cells)

Signs of anaemia:

- Feeling more tired, weak or generally unwell than normal
- Feeling short of breath.

What to do: Your doctor will make sure you continue to have regular blood tests to check for this side effect. Tell your doctor if you notice these symptoms as some cases of anaemia requiring blood transfusion have also been reported.

Liver damage —this side effect is uncommon, affecting less than 1 in 100 people who take Volibris.

Signs that your liver might not be working properly:

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

What to do: Your doctor will make sure you continue to have regular blood tests to check for this side effect.

Tell your doctor straight away if you notice any of these symptoms, or if they happen suddenly after taking Volibris.

Continued overleaf...

Possible side effects of Volibris *continued*

Allergic reactions — these are common, affecting up to 1 in 10 who take Volibris.

Signs of an allergic reaction:

- A skin rash
- Itching or swelling (usually of the face, lips, tongue or throat) which may cause difficulty breathing or swallowing.

Hypotension – these are common, affecting up to 1 in 10 who take Volibris

Signs that you may have Hypotension:

- Dizziness or lightheadedness
- Nausea
- Cold, clammy, pale skin
- Fainting (syncope)
- Blurred vision
- Lack of concentration
- Rapid, shallow breathing

What to do: Get medical help straight away if you notice any of these symptoms, especially if they happen suddenly after you take Volibris.

If you have any other symptoms that concern you:

Tell your doctor, whether or not you think the symptoms may be a side effect of Volibris.

To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via sa.aermi-saudi@gsk.com or by calling Saudi Arabia (+966 1 26536666).”

Or you can report to the SFDA through:

- Toll free phone: 800249000
- Fax: +966112057662
- E-mail: npc.drug@sfda.gov.sa
- Online: <https://ade.sfda.gov.sa/>

Blood test appointments

While you are taking Volibris, you need to have regular blood tests:

- To check how well your liver is working. These tests are recommended every month.
- To check whether you are anaemic (with a reduced number of red blood cells). These tests are recommended after 1 and 3 months of treatment, and from time to time after that.

Patient's details (your doctor will complete this section)

Start date of Volibris

Baseline liver function test results

ALT

AST

Baseline blood count results

Haemoglobin

Haematocrit

Pregnancy test results

If you are a woman who could become pregnant, you will also need to have regular (e.g. monthly) pregnancy tests

Pregnancy test

Notes

Notes of normal ranges (blood tests)			
	Hb	ALT	AST
Adult Female	11.5 - 16g/dL	5 - 38 i.u./L	6 - 34 i.u./L
Adult Male	13.3 - 18g/dL	10 - 50 i.u./L	8 - 40 i.u./L

These figures are provided as a guide only, as normal ranges can vary by laboratory.

Pocket leaflet for partners of female patients appears here
with the following message printed on it:

**This leaflet should be given to
Partners of female patients**

If you experience any unwanted side effects (even those not listed in the patient information booklet) or if any of the side effects become troublesome while you are taking Volibris, please tell your doctor as soon as possible.

This booklet is provided as a service to patients by GlaxoSmithKline

To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via sa.aermi-saudi@gsk.com or by calling Saudi Arabia (+966 1 26536666).”

Or you can report to the SFDA through:

- **Toll free phone: 800249000**
- **Fax: +966112057662**
- **E-mail: npc.drug@sfd.gov.sa**
- **Online: <https://ade.sfd.gov.sa/>**