

TAKING VOLIBRIS

(AMBRISENTAN)

WHAT YOU NEED TO KNOW



Information for patients who have been prescribed Volibris



Volibris
ambrisentan

This booklet is to be kept in the doctor's consultation room and to be given only by doctors to patients who have been prescribed with Volibris.

Patient Information

Your details

Name :

Address :

Telephone Number :

Your GP's details

GP's Name :

GP's Address :

GP's Telephone Number :

Your pulmonary arterial hypertension (PAH) specialist centre information

This section should be completed by the prescribing doctor

Hospital :

Consultant :

Pulmonary Nurse :

Clinic :

Department :

Hospital Address :

Telephone (Appointments) :

Telephone (Information) :

Telephone (Emergency) :

Telephone (Hospital Pharmacy) :

ABOUT
ME

INTRODUCTION

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

Read it carefully.

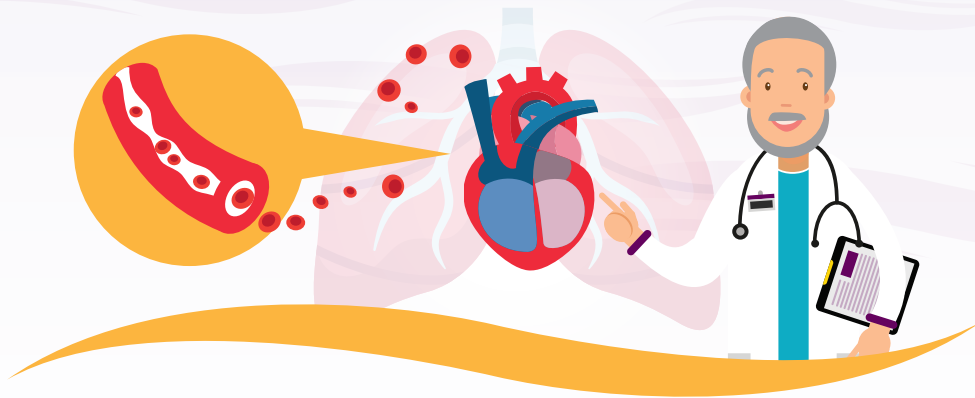
- Keep this booklet with you while you are taking Volibris.
- If you see a doctor who is not your usual healthcare provider, show them this card.
- If there's anything here that you don't understand, or if you have any more questions, talk to your doctor, specialist nurse or pharmacist.

PLEASE TAKE THIS BOOKLET WITH YOU TO ALL YOUR APPOINTMENTS

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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** or significantly **raised liver enzymes**.
- 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** or any other contents of the tablet such as the colouring agent Allura red AC Aluminium Lake.
- if you have **scarring of the lungs** of unknown cause (idiopathic pulmonary fibrosis).

Speak to your doctor:

- if you have or have had **liver disease**.
- if you have or have had a **low number of red blood cells** (anaemia).
- if you have **swelling (oedema)** especially of the ankles and feet.
- if you have **kidney disease**.
- if you are **taking other medicines**.
- if you have **right heart failure**.
- if you have or have had **low blood pressure**.

HOW TO TAKE VOLIBRIS?



Always take Volibris exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

- **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 that the tablet is swallowed whole** and not be split, crushed or chewed.
- **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 to attend clinic regularly, as recommended by your health care team.**
- **You may need regular blood tests:**
 - to check how well your liver is working.
- **Your doctor may also take blood tests:**
 - if you have signs that your liver is not working properly.
 - to check whether you are anaemic (have a low red blood cell count). These blood tests are recommended before you start taking Volibris, at 1 month of treatment, and from time to time after that. Your doctor will make sure these happen when needed.

It is important that you have these blood tests as advised by your doctor.

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 BREAST-FEEDING

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 3 months 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 an **effective form of contraception** (birth control) while you are taking Volibris. It's preferable that you and your partner use two complementary methods of contraception e.g. double barrier method (male condom combined with female diaphragm with or without a vaginal spermicidal agent) plus one other (e.g. oral contraceptive). 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 3 months 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**.
- Tell your doctor if you are breast-feeding or plan to breast-feed. Your doctor can discuss with you the risks and benefits involved.

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

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 and whether you are taking Volibris in combination with any other medicines.

Not all possible side effects are listed here.

The most common side effects include:



Anaemia
(reduced number of red blood cells)



Swelling (oedema), especially of the ankles and feet



Dizziness, headache, fatigue



Palpitations
(fast or irregular heartbeats)



Flushing
(redness of the skin)



Blocked nose
and other nasal symptoms



Stomach pain, nausea, vomiting and diarrhoea



Chest pain/discomfort

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. If you notice any side effects not mentioned here while taking Volibris or any of the mentioned side effects worries you, please tell your doctor or pharmacist.

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



Raised liver enzymes — the side effect is common, affecting up to 1 in 10 people who take Volibris.

Liver Injury and Inflammation of the Liver — the frequency of liver damage associated with the use of Volibris is unknown as events have been reported voluntarily from post-marketing experiences, from a population of unknown size.

Signs that your liver might not be working properly:



Loss of appetite



Feeling sick
or being sick
(nausea or vomiting)



High temperature
(fever)



Pain in the stomach
(abdominal pain)



Yellowing of your skin or the whites
of your eyes
(jaundice)



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.



Allergic reactions — these are common, affecting up to 1 in 10 people 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

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.

Contact your doctor immediately if you experience any side effects. Do not stop the medication until you have consulted your doctor.



BLOOD TEST APPOINTMENTS



While you are taking Volibris, you may need to have your blood tested:

- **To check how well your liver is working.** These tests will be done based on your doctor's determination of necessity.
- **To check whether you are anaemic** (with a reduced number of red blood cells). These blood tests are recommended before you start taking Volibris, at 1 month of treatment, and from time to time after that.

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.

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Volibris *ambrisentan*

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For further information, please consult your doctor or pharmacist
For reporting of adverse events please write to sg.drugsafety@gsk.com
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GlaxoSmithKline Pte Ltd, 23 Rochester Park, Singapore 139234
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