

PATIENT INFORMATION ON

AMBRISENTAN

(Brand name: Volibris)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **how you should take your medicine**
- **the possible side effects**
- **what tests you will have to monitor your condition**
- **other precautions you should take while you are taking ambrisentan.**

Please read it carefully and discuss it with your doctor.

Important things to remember:

- While taking ambrisentan you should see your treating specialist regularly to make sure the treatment is working as it should, and to minimise any possible side effects.
- Ambrisentan should be taken at the same time each day.
- You should not stop your treatment unless your doctor tells you to.
- You should not increase or reduce the dose of ambrisentan unless your doctor tells you to.
- Contact your doctor at once if you experience symptoms such as nausea, stomach pain, low fever, loss of appetite, dark urine, clay-coloured stools or jaundice (yellowing of the skin or eyes).

For more information about SCLERODERMA and other inflammatory conditions see Arthritis Australia's website
www.arthritisaustralia.com.au

What is ambrisentan?

Ambrisentan (brand name Volibris) is a medicine used to treat a condition called pulmonary arterial hypertension (PAH). This is a condition where there is increased pressure in the arteries that carry blood from the heart to the lungs.

PAH can occur in a number of rheumatological diseases such as scleroderma. These diseases can cause thickening of the blood vessel walls. Symptoms include shortness of breath during routine activity, (such as climbing stairs), tiredness and chest pain.

How does it work?

Ambrisentan helps lower blood pressure in the lungs by preventing thickening of the blood vessels. This helps your heart pump blood through the blood vessels in the lungs more efficiently.

What benefit can you expect from your treatment and how is it monitored?

Ambrisentan can reduce the symptoms of PAH and in some cases prolong life expectancy. It may take up to 2 months or more before your symptoms start to improve.

Before ambrisentan can be prescribed, you will be assessed by a specialist such as a rheumatologist, immunologist, cardiologist (heart) or respiratory (lung) physician with experience in managing PAH.

You will be asked to have the following tests:

- an ultrasound scan of your heart (echocardiogram)

- a right heart catheter - this is a test to measure the blood pressures in your heart and lungs. It involves inserting a tube into your heart from an artery in your neck or groin.
- a six minute walk test (6MWT) to measure how far you can walk in six minutes.

Every six months you will be asked to have the echocardiogram and the 6MWT to check that ambrisentan is still helping your condition.

How is ambrisentan taken?

Ambrisentan comes as a tablet in two strengths, 5mg and 10mg.

What is the dosage and when should it be taken?

The normal starting dose is 5mg once a day. In some cases the dose may be increased by your doctor to 10mg once a day.

Ambrisentan should be taken at the same time each a day. If you forget to take a tablet you can take it later in the day. If it is the next day, take the normal dose (do not take a double dose). It does not have to be taken with food.

Can other medicines be taken with ambrisentan?

Ambrisentan may be taken in combination with other medicines, including:

- steroid medicines such as prednisolone or cortisone injections into the joint
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen)
- simple pain relieving medicines such as paracetamol
- calcium channel blockers (for Raynaud's disease)
- diuretics (fluid tablets)
- warfarin (blood-thinning medicine) see *Precautions*
- other treatments for PAH.

There are a number of medicines that should **not** be taken when you are taking ambrisentan (see *Precautions*). There are also separate information sheets for the medicines mentioned above.

How long is the treatment continued?

Ambrisentan may be given on a long term basis provided it does not cause problems and continues to help your condition. It is usually

given for as long as the 6-monthly tests (echocardiogram and 6MWT) show that it is of benefit.

Do not stop taking ambrisentan without first talking to your doctor. If your doctor does decide to stop the treatment you may need to reduce the dose gradually before you stop the medicine completely.

Are there any side effects?

Most people who take ambrisentan do not experience side effects. Tell your doctor if you are concerned about possible side effects. A reduction in dose may minimise the side effects so that you can continue to have this treatment.

Most common possible side effects

- The most common side effects include *stomach upset, nausea, diarrhea* and *headache*.
- Other side effects include *inflamed throat, irritated nose passages or skin rash*.
- *Dizziness* due to low blood pressure, *flushing, ankle and/or leg swelling* can occur.
- *Irregular heartbeats* or *tiredness* have been reported.

Less common or rare possible side effect

- Ambrisentan can cause severe *liver problems*. Symptoms include nausea, stomach pain, low grade fever, loss of appetite, dark urine, clay-colored stools and jaundice (yellowing of the skin or eyes). Call your doctor at once if you have any of these symptoms.
- Low haemoglobin (*anaemia*) can be detected on blood tests but rarely causes symptoms.
- There are also a number of other uncommon side effects. It is a good idea to read the leaflet that comes with the medicine as it will list all the precautions and possible side effects.

What precautions are necessary?

Blood tests

- Your liver function and blood counts for haemoglobin will need to be tested before you start taking ambrisentan, and again each month during your treatment.

Use with other medicines

- Ambrisentan can interact with other medicines. You should tell your doctor

(including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

- You should also mention your treatment when you see other health professionals.
- The following medicines may interfere with ambrisentan. Some should not be taken with ambrisentan. For others, the dose may need to be adjusted.
 - cyclosporin (Cicloral, Neoral, Sandimmune)
 - cholesterol lowering medicines
 - anti-fungal medicines (ketoconazole, fluconazole, itraconazole or voriconazole)
 - HIV/AIDS medicines lopinavir or ritonavir (Kaletra, Norvir)
 - tacrolimus (used to prevent rejection of liver or kidney transplants)
 - rifampicin (used for tuberculosis).
- Ambrisentan does not increase the risk of side effects from low dose aspirin (taken for prevention of heart attack and strokes).
- Ambrisentan can be taken safely with anti-inflammatory drugs (NSAIDs) provided your kidney function is normal.

- The simple pain reliever paracetamol and combined medicines such as Panadeine and Panadeine Forte can be used while taking ambrisentan provided you take them as directed.
- Most vaccines can be given safely with ambrisentan. Pneumovax and yearly flu vaccinations are safe and recommended to reduce your risk of those infections. Talk with your rheumatologist before receiving any vaccines.

Use during pregnancy and breastfeeding

- Ambrisentan should not be taken during pregnancy or when breastfeeding.
- If you are a woman of child bearing age you should use effective contraception while taking ambrisentan.
- If you are planning a family or you become pregnant during your treatment, you should discuss this with your doctor as soon as possible.

How to store ambrisentan

- Store ambrisentan at room temperature, away from heat, moisture and light (e.g. not in the bathroom).
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your specialist regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.