

Package leaflet: Information for the patient

Ambrisentan 5 mg film-coated tablets Ambrisentan 10 mg film-coated tablets

ambrisentan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Ambrisentan is and what it is used for

The name of the product is Ambrisentan film-coated tablets (called Ambrisentan throughout this leaflet). These tablets contain 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, adolescents and children aged 8 years and over. 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.

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

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

2. What you need to know before you take Ambrisentan

Do not take Ambrisentan:

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

Talk to your doctor or pharmacist before taking Ambrisentan if you have:

- liver problems,
- anaemia (a reduced number of red blood cells),
- swelling in the hands, ankles or feet caused by fluid (peripheral oedema),
- lung disease where the veins in the lungs are blocked (pulmonary veno-occlusive disease).

→ **Your doctor will decide** whether Ambrisentan is suitable for you.

You will need regular blood tests

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

- whether you have anaemia,
- whether your liver is working properly.

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

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

Do not give this medicine to children aged under 8 years as the safety and effectiveness is not known in this age group.

Other medicines and Ambrisentan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to adjust your dose of Ambrisentan 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 Ambrisentan.

If you are taking other medicines 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

Ambrisentan 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 Ambrisentan. Talk to your doctor about this.

→ **Do not take Ambrisentan if you are pregnant or planning to become pregnant.**

→ **If you become pregnant or think that you may be pregnant** while you are taking Ambrisentan, 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 Ambrisentan and regularly while you are taking this medicine.

Breast-feeding

It is not known if the active substance, ambrisentan can pass into breast milk.

→ **Do not breast-feed while you are taking Ambrisentan.** Talk to your doctor about this.

Fertility

If you are a man taking Ambrisentan, 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

Ambrisentan 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.**

Ambrisentan contains lactose monohydrate, soya lecithin and Allura red AC (E129)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

This medicine contains soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

This medicine contains a colouring called Allura red AC (E129) which may cause allergic reactions.

3. How to take Ambrisentan

Always take this medicine exactly as your doctor or pharmacist has told you to.

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

How much Ambrisentan to take

Adults

The usual dose of Ambrisentan is one 5 mg tablet, once a day. Your doctor may decide to increase your dose to 10 mg (two 5 mg tablet or one 10 mg tablet), once a day.

If you take ciclosporin A, do not take more than one 5 mg tablet of Ambrisentan, once a day.

Adolescents and children aged 8 years to less than 18 years

Usual starting dose of Ambrisentan	
Weighing 35 kg or more	One 5 mg tablet, once a day
Weighing at least 20 kg, and less than 35 kg	One 2.5 mg* tablet, once a day

Your doctor may decide to increase your dose. It's important that children attend their regular doctor's appointments, as their dose needs to be adjusted as they get older or gain weight. If taken in combination with cyclosporin A, the dose of Ambrisentan for adolescents and children weighing less than 50 kg will be limited to 2.5 mg* once daily, or 5 mg once daily if they weigh 50 kg or more.

* For doses requiring 2.5 mg strength, another product available on the market should be used.

How to take Ambrisentan

It is best to take your tablet at the same time each day. Swallow the tablet whole, with a glass of water, do not split, crush or chew the tablet. You can take Ambrisentan with or without food.

If you take more Ambrisentan than you should

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 Ambrisentan

If you forget a dose of Ambrisentan, just take the tablet as soon as you remember, then carry on as before.

→ **Do not take a double dose at the same time to make up for a forgotten dose.**

If you stop taking Ambrisentan

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

→ **Do not stop taking Ambrisentan 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor if you get any of these:

Allergic reactions

This is a common side effect that may affect **up to 1 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 1 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 1 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 1 in 10** people.

Hypotension (low blood pressure)

This can cause light-headedness. This is a common side effect that may affect **up to 1 in 10** people.

→ **Tell your doctor straight away** if you (or your child) get these effects or if they happen suddenly after taking Ambrisentan.

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'.

Other side effects

Very common (may affect more than 1 in 10 people):

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

In combination with tadalafil (another PAH medicine)

In addition to the above:

- flushing (redness of the skin),
- being sick (vomiting),
- chest pain/discomfort.

Common (may affect up to 1 in 10 people):

- 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,
- nose bleed,
- rash.

In combination with tadalafil

In addition to the above, except abnormal blood test results for liver function:

- ringing in the ears (tinnitus) only when taking the combination treatment.

Uncommon (may affect up to 1 in 100 people):

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

In combination with tadalafil

- sudden hearing loss.

Side effects in children and adolescents

These are expected to be similar to those listed above for adults.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ambrisentan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

White PVC/PVDC/ aluminium blisters:

This medicinal product does not require any special temperature storage conditions. Store in the original blister packaging to protect from light.

Transparent PVC/PE/PVDC/ aluminium blisters:

This medicinal product does not require any special temperature storage conditions. Store in the original packaging to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your

pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ambrisentan contains

The active substance is ambrisentan.

Ambrisentan 5 mg film-coated tablets:

Each tablet contains 5 mg ambrisentan.

Ambrisentan 10 mg film-coated tablets:

Each tablet contains 10 mg ambrisentan.

The other ingredients are:

Tablet core: cellulose, microcrystalline (E460); lactose monohydrate; croscarmellose sodium (E468); magnesium stearate (E572).
Tablet coat: polyvinyl alcohol (E1203), titanium dioxide (E171); macrogol MW3350/ polyethylene glycol (E1521); talc (E553b); Allura red AC (E129); lecithin (soya) (E322).

What Ambrisentan looks like and contents of the pack

Ambrisentan 5 mg film-coated tablets:

Pale pink square convex film-coated tablets, debossed with "5" on one side, plain on the other side with a nominal length/width of approximately 5.9 mm.

Ambrisentan 10 mg film-coated tablets:

Pink oblong biconvex film-coated tablets, debossed with "10" on one side, plain on the other side with a nominal length of approximately 11.1 mm, a nominal width of approximately 5.6 mm.

Ambrisentan is packed in white PVC/ PVDC/ aluminium blisters and/or transparent PVC/ PE/ PVDC/ aluminium blisters.

Pack size: cardboard boxes containing 10, 30 film-coated tablets in blisters or 10x1, 30x1 film-coated tablets in unit dose blisters. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP
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