

## Ambrisentan 5mg Film-coated tablets Ambrisentan 10mg 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Ambrisentan 5mg, 10mg Film-coated tablets but within this leaflet, it will be referred to as Ambrisentan tablets.

**What is in this leaflet:**

- 1 What Ambrisentan tablets are and what they are used for**
- 2 What you need to know before you take Ambrisentan tablets**
- 3 How to take Ambrisentan tablets**
- 4 Possible side effects**
- 5 How to store Ambrisentan tablets**
- 6 Contents of the pack and other information**

### 1 What Ambrisentan tablets are and what they are used for

Ambrisentan tablets contain the active substance ambrisentan. They belong to a group of medicines called other antihypertensives (used to treat high blood pressure).

They are 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 tablets widen the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

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

### 2 What you need to know before you take Ambrisentan tablets

**Do not take Ambrisentan tablets if:**

- you are **allergic** to ambrisentan, soya, or any of the other ingredients of this medicine (listed in section 6)
- **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'
- you are **breast-feeding**. Read the information under 'Breast-feeding'
- you **have liver disease**. Talk to your doctor, who will decide whether this medicine is suitable for you
- you have **scarring of the lungs** of unknown cause (idiopathic pulmonary fibrosis).

**Warnings and precautions**

Talk to your doctor before taking this medicine:

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

**Your doctor will decide** whether Ambrisentan tablets are suitable for you.

**You will need regular blood tests**

Before you start taking Ambrisentan tablets 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 tablets.

**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 tablets**

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

If you start taking cyclosporine A (a medicine used after transplant or to treat psoriasis), your doctor may need to adjust your dose of Ambrisentan tablets.

If you are taking rifampicin (an antibiotic used to treat serious infections) your doctor will monitor you when you first start taking Ambrisentan tablets.

If you are taking other medicines used 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 tablets 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 tablets. Talk to your doctor about this.

**Do not take Ambrisentan tablets 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 tablets, **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 tablets and regularly while you are taking this medicine.

**Breast-feeding**

It is not known if the active substance of Ambrisentan tablets can pass into breast milk.

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

**Fertility**

If you are a man taking Ambrisentan tablets, 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 tablets 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 tablets contain lactose, lecithin (soya), allura red AC aluminium lake (E129) and sodium.**

Ambrisentan tablets contain small amounts of a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, **contact your doctor** before taking this medicinal product.

Ambrisentan tablets contain lecithin derived from soya. If you are allergic to soya, do not use this medicine (see section 2 'Do not take Ambrisentan tablets').

Ambrisentan tablets contain a colouring called allura red AC aluminium lake (E129). This can cause allergic reactions (see section 4).

Ambrisentan tablets contain less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

### 3 How to take Ambrisentan tablets

**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 many Ambrisentan tablets to take Adults**

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

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

**Adolescents and children aged 8 years to less than 18 years**

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

\*Use of other ambrisentan 2.5 mg tablets available in the market is recommended for 2.5mg dose as this dose is not feasible with Ambrisentan 5mg, 10mg Film-coated tablets.

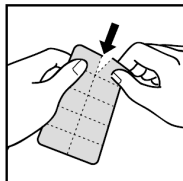
**How to take Ambrisentan tablets**

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 tablets with or without food.

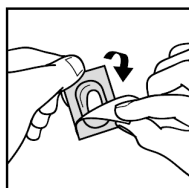
**Taking out a tablet from a blister pack**

These tablets come in a special packaging to prevent children removing them.

1. Separate one blister cavity from the blister package by tearing it along the perforation.



2. Peel off the lidding foil and take out the tablet.



#### **If you take more Ambrisentan tablets 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 tablets**

If you forget a dose of Ambrisentan tablets, 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.**

#### **Do not stop taking Ambrisentan tablets without your doctor's advice.**

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

#### **Do not stop taking Ambrisentan tablets 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. This is a common side effect that may affect **up to 1 in 10** people. Symptoms include:

- shortness of breath
- extreme tiredness
- swelling in the ankles and legs.

#### **Reduced number of red blood cells (anaemia)**

This is a very common side effect that may affect **more than 1 in 10** people. Sometimes this requires a blood transfusion. Symptoms include:

- tiredness and weakness
- shortness of breath
- generally feeling unwell.

#### **Low blood pressure (hypotension)**

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

- light-headedness.

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

**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)
- shortness of breath getting worse shortly after starting Ambrisentan tablets
- 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).

#### **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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 tablets**

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.

This medicine does not require any special storage conditions.

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 tablets contain**

##### Ambrisentan 5mg Film-coated tablets:

- The active substance is ambrisentan. Each Film-coated tablet contains 5mg ambrisentan.
- The other ingredients are: Tablet core: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate. Film coat: polyvinyl alcohol-partial hydrolysed, titanium dioxide (E171), talc, macrogol, lecithin (soya) (E322), allura red AC aluminium lake (E129).

##### Ambrisentan 10mg Film-coated tablets:

- The active substance is ambrisentan. Each Film-coated tablet contains 10mg ambrisentan.
- The other ingredients are: Tablet core: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate. Film coat: polyvinyl alcohol-partial hydrolysed, titanium dioxide (E171), talc, macrogol, lecithin (soya) (E322), allura red AC aluminium lake (E129).

#### **What Ambrisentan tablets look like and contents of the pack**

##### Ambrisentan 5mg Film-coated tablet

Ambrisentan 5mg Film-coated tablet is a light pink, round, biconvex film-coated tablet debossed with '5' on one side and with a dimension of approximately 7.0mm.

##### Ambrisentan 10mg Film-coated tablet

Ambrisentan 10mg Film-coated tablet is a deep pink, oval, biconvex film-coated tablet debossed with '10' on one side and with a dimension of approximately 9.9mm x 5.0mm.

Ambrisentan tablets are supplied as 5mg and 10mg Film-coated tablets in unit dose blister packs (Aluminium/Aluminium foil blisters or PVC/PVDC/Aluminium foil blisters) of 10x1 or 30x1 tablets.

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**If you would like a leaflet with larger text, please contact +44 (0) 1271 385257.**