Package leaflet: Information for the patient

<Invented name> 5 mg film-coated tablets
<Invented name> 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, 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.

What is in this leaflet

1. What <invented name> is and what it is used for

<Invented name> contains the active substance ambrisentan. It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure).

<Invented name> it is used to treat pulmonary arterial hypertension (PAH) in adults. 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.

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

<Invented name> may also be used in combination with other medicines used to treat PAH.

2. What you need to know before you take <invented name>

Do not take <invented name>

- if you are **allergic** to ambrisentan 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 before taking this medicine if you have:

- liver problems
- anaemia (a reduced number of 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 <invented name> is suitable for you.

<u>You will need regular blood tests</u>
Before you start taking <invented name> 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 <invented name>.

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 and adolescents

<Invented name> is not recommended for children and adolescents aged under 18 years as the safety and effectiveness is not known in this age group.

Other medicines and <invented name>
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 <invented name>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 <invented name>.

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
<Invented name> 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 <invented name>. Talk to your doctor about this.

Do not take <invented name> if you are pregnant or plannig to become pregnant.

If you become pregnant or think that you may be pregnant while you are taking <invented name> **see your doctor immediately.**

If you are a woman who could become pregnant, your doctor will ask you to take pregnancy test before you start taking <invented name> and regularly while you are taking this medicine.

Breast-feeding
It is not known if <invented name> is transferred to breast milk.

Do not breast-feed while you are taking <invented name>. Talk to your doctor about this.

Fertility
If you are a man taking <invented name>, 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
<Invented name> 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.

<Invented name> contains lactose
If you have been told by your doctor that you have an intolerance to some sugars contact you doctor before taking this medicine.

3. How to take <invented name>

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 <invented name> to take
The usual dose of <invented name> is one 5 mg tablet, once a day. Your doctor may decide to increase your dose to 10 mg, once a day.

If you take cyclosporine A, do not take more than one 5 mg tablet of <invented name>, once a day.

How to take <invented name>
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 <invented name> with or without food.

If you take more <invented name> 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 <invented name>
If you forget a dose of <invented name>, just take the tablet as soon as you remember, then carry on as before.

Do not take two tablets at the same time to make up for a forgotten dose.

Do not stop taking <invented name> without your doctor's advice.
<Invented name> is a treatment that you will need to keep on taking to control your PAH.

Do not stop taking <invented name> 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.

Conditions you and your doctor need to look out for:

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 get these effects or if they happen suddenly after taking <invented name>.

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 include
Very common side effects:
- headache
- dizziness
- palpitations (fast or irregular heart beats)
- worsening shortness of breath shortly after starting <invented name>.
- 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 side effects:
- 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 side effects:
- liver injury
- inflammation of the liver caused by the body's own defences (autoimmune hepatitis)

In combination with tadalafil
- sudden hearing loss.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

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 <invented name> contains

The active substance is ambrisentan.
Each film-coated tablet contains 5 mg or 10 mg of ambrisentan.

The other ingredients are lactose monohydrate, microcrystalline cellulose (E 460(i)), pregelatinised maize starch, magnesium stearate (E 470b), polyvinyl alcohol (E 1203), titanium dioxide (E 171), macrogol (E 1521), talc (E 553b) and red iron oxide (E 172).

What <invented name> looks like and contents of the pack

<Invented name> 5 mg is a pink, circular, film-coated tablet with “5” debossed on one side.

<Invented name> 10 mg is a pink, oval shaped, film-coated tablet with “10” debossed on one side.

<Invented name> 5 mg and 10 mg is supplied in blisters of 10 or 30 film-coated tablets or perforated unit dose blisters of 10 x 1, or 30 x 1 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
<[To be completed nationally]>

Manufacturer
<[To be completed nationally]>

This medicine is authorised in the Member States of the European Economic Area under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in XX/YYYY.