

## Package leaflet: Information for the user

### Ambrisentan Genepharm 5 mg, filmomhulde tabletten Ambrisentan Genepharm 10 mg, filmomhulde tabletten

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

#### **1. What [Product Name] is and what it is used for**

[Product Name] contains 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.

[Product 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.

[Product Name] may also be used in combination with other medicines used to treat PAH.

#### **2. What you need to know before you take [Product Name]**

##### **Do not take [Product Name]:**

- If you are **allergic** to ambrisentan, or 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 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 [Product Name] is suitable for you.

### **You will need regular blood tests**

Before you start taking [Product Name], and at regular intervals while you're 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 [Product 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**

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 [Product Name]**

**Tell your doctor or pharmacist** if you're 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 [Product Name].

If you're taking **rifampicin** (an antibiotic used to treat serious infections) your doctor will monitor you, when you first start taking [Product Name].

If you're taking other medicines used to treat PAH (e.g. iloprost, epoprostenol, sildenafil) your doctor might need to monitor you.

→ **Tell your doctor or pharmacist** if you are taking any of these medicines.

### **Pregnancy**

[Product 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're taking [Product Name]. Talk to your doctor about this.

→ **Don't take [Product Name] if you are pregnant or planning to become pregnant.**

→ **If you become pregnant or think that you may be pregnant** while you're taking [Product Name], **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 [Product Name] and regularly while you are taking this medicine.

### **Breast-feeding**

It is not known if the active substance of [Product Name] can pass into breast milk.

→ **Don't breast-feed while you're taking [Product Name].** Talk to your doctor about this.

### **Fertility**

If you are a man taking [Product 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**

[Product 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.

→ **Don't drive or use machines if you're feeling unwell.**

### **[Product Name] contains lactose.**

[Product Name] film-coated 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.

**[Product Name] film-coated tablets contain lecithin derived from soya.**

If you are allergic to soya, do not use this medicine (see section 2 ‘Do not take [Product Name]’).

**[Product Name] contains a colouring called Allura red AC aluminium lake (E129).**

This may cause allergic reactions (see section 4).

**[Product Name] contains sodium.**

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

### **3. How to take [Product Name]**

**Always take this medicine exactly as your doctor or pharmacist has told you to.** Check with your doctor or pharmacist if you’re not sure.

#### **How much [Product Name] to take**

##### **Adults**

The usual dose of [Product Name] is one 5 mg film-coated 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 film-coated tablet of [Product Name], once a day.

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

<b>Usual starting dose of [Product Name]</b>	
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*</b> mg tablet, once a day

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

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 [Product Name] 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.

#### **How to take [Product 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 [Product Name] with or without food.

#### **If you take more [Product 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 [Product Name]**

If you forget a dose of [Product Name], just take the tablet as soon as you remember, then carry on as before.

→ **Don't take a double dose at the same time to make up for a forgotten dose.**

**If you stop taking [Product Name]**

[Product Name] is a treatment that you will need to keep on taking to control your PAH.

→ **Don't stop taking [Product 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.

##### **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 [Product 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**

**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 [Product 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** (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 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 [Product 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 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 [Product Name] contains**

The active substance is ambrisentan.

Each film-coated tablet contains 5 or 10 mg.

The other ingredients are: microcrystalline cellulose (E460), lactose monohydrate, croscarmellose sodium (E468), magnesium stearate (E572), polyvinyl alcohol, titanium dioxide (E171), Macrogol/polyethylene glycol (E1521), talc (E553b), Allura red AC (E129) and lecithin (soya) (E322).

#### **What [Product Name] looks like and contents of the pack**

[Product Name] 5 mg film-coated tablet is a pale pink, square, convex film-coated tablet debossed with '5' on one side, plain on the other side with a normal length/width of 5.9 approximately mm.

[Product Name] 10 mg film-coated tablet is a pink oblong biconvex film-coated tablet, debossed with “10” on one side, plain on the other side with a nominal length of approximately 11.1 mm and a nominal width of approximately 5.6 mm.

[Product Name] is supplied as 5 mg and 10 mg film-coated tablets in packs containing 10 or 30 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Genepharma S.A.  
18<sup>th</sup> km Marathonos Avenue, Pallini  
15351, Athene  
Griekenland

### **Manufacturer**

Genepharma S.A.  
18<sup>th</sup> km Marathonos Avenue, Pallini  
15351, Athene  
Griekenland

Delorbis Pharmaceuticals Ltd  
17 Athinon str.  
Ergates Industrial Area  
2643 Ergates, Lefkosia  
Cyprus

### **In het register ingeschreven onder:**

Ambrisentan Genepharma 5 mg, filmomhulde tabletten	RVG 123889
Ambrisentan Genepharma 10 mg, filmomhulde tabletten	RVG 123890

**Deze bijsluiter is voor het laatst goedgekeurd in maart 2024.**