

## **Package leaflet: Information for the patient**

**Ambrisentan Zentiva 5 mg filmomhulde tabletten**

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

#### **1. What Ambrisentan Zentiva is and what it is used for**

Ambrisentan Zentiva 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.

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

#### **2. What you need to know before you take Ambrisentan Zentiva**

### **Do not take Ambrisentan Zentiva:**

- 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 Zentiva 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 Zentiva is suitable for you.

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

Before you start taking Ambrisentan Zentiva, 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 Zentiva.

### **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 Zentiva**

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 Zentiva 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 Zentiva.

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 Zentiva 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 Zentiva. Talk to your doctor about this.

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

### **Breast-feeding**

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

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

### **Fertility**

If you are a man taking Ambrisentan Zentiva, 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 Zentiva 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 Zentiva 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 Zentiva

**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 Ambrisentan Zentiva to take

##### Adults

The usual dose of Ambrisentan Zentiva 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 cyclosporine A, do not take more than one 5 mg tablet of Ambrisentan Zentiva, once a day.

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

Usual starting dose of Ambrisentan Zentiva	
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 Zentiva 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 Zentiva

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 Zentiva with or without food.

#### If you take more Ambrisentan Zentiva 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 Zentiva

If you forget a dose of Ambrisentan Zentiva, 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 Zentiva**

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

→**Do not stop taking Ambrisentan Zentiva 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 Zentiva.

**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,
- nosebleed,
- 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 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 Ambrisentan Zentiva**

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 Zentiva contains**

The active substance is ambrisentan.

#### Ambrisentan Zentiva 5 mg film-coated tablets:

Each tablet contains 5 mg ambrisentan.

#### Ambrisentan Zentiva 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 MW 3350/ polyethylene glycol (E1521); talc (E553b); Allura red AC (E129); lecithin (soya) (E322).

### **What Ambrisentan Zentiva looks like and contents of the pack**

Ambrisentan Zentiva 5 mg filmomhulde tabletten:

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 Zentiva 10 mg filmomhulde tabletten:

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 Zentiva 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 10×1, 30×1 film-coated tablets in unit dose blisters.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Zentiva, k.s.  
U Kabelovny 130  
Dolní Měcholupy,  
102 37 Praag 10  
Tsjechie

### **Manufacturer**

Geneparm S.A.  
18 km Marathonos Ave  
153 51 Pallini Attiki  
Griekenland

of

Delorbis Pharmaceuticals Ltd  
17 Athinon str.



Ergates Industrial Area

2643 Ergates

Lefkosia

Cyprus

**This medicine is authorised in the Member States of the European Economic Area and in the under the following name: Ambrisentan Zentiva**

**Deze bijsluiter is voor het laatst goedgekeurd in maart 2022**