

## Package leaflet: Information for the patient

**Edoxaban Zentiva 15 mg film-coated tablets**  
**Edoxaban Zentiva 30 mg film-coated tablets**  
**Edoxaban Zentiva 60 mg film-coated tablets**  
edoxaban

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

#### 1. What Edoxaban Zentiva is and what it is used for

Edoxaban Zentiva contains the active substance edoxaban and belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming. It works by blocking the activity of factor Xa, which is an important component of blood clotting.

Edoxaban Zentiva is used in adults to:

- **prevent blood clots in the brain (stroke) and other blood vessels in the body** if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor, such as heart failure, previous stroke or high blood pressure;
- **treat blood clots in the veins of the legs (deep vein thrombosis) and in the blood vessels in the lungs (pulmonary embolism), and to prevent blood clots from re-occurring** in the blood vessels in the legs and/or lungs.

#### 2. What you need to know before you take Edoxaban Zentiva

##### Do not take Edoxaban Zentiva

- if you are allergic to edoxaban or any of the other ingredients of this medicine (listed in section 6);
- if you are actively bleeding;
- if you have a disease or condition that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, or recent surgery of the brain or eyes);
- if you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open;

- if you have a liver disease which leads to an increased risk of bleeding;
- if you have uncontrolled high blood pressure;
- if you are pregnant or breast feeding.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Edoxaban Zentiva:

- if you have an increased risk of bleeding, as could be the case if you have any of the following conditions:
  - end stage kidney disease or if you are on dialysis;
  - severe liver disease;
  - bleeding disorders;
  - a problem with the blood vessels in the back of your eyes (retinopathy);
  - recent bleeding in your brain (intracranial or intracerebral bleeding);
  - problems with the blood vessels in your brain or spinal column;
- if you have a mechanical heart valve.

Edoxaban Zentiva 15 mg is only to be used when changing from Edoxaban Zentiva 30 mg to a vitamin K antagonist (e.g. warfarin) (see section 3. How to take Edoxaban Zentiva).

Take special care with Edoxaban Zentiva,

- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk for blood clots), tell your doctor who will decide if the treatment may need to be changed.

If you need to have an operation,

- it is very important to take Edoxaban Zentiva before and after the operation exactly at the times you have been told by your doctor. If possible, Edoxaban Zentiva should be stopped at least 24 hours before an operation. Your doctor will determine when to restart Edoxaban Zentiva. In emergency situations your physician will help determine the appropriate actions regarding Edoxaban Zentiva.

### **Children and adolescents**

Edoxaban Zentiva is not recommended for children and adolescents under 18 years of age.

### **Other medicines and Edoxaban Zentiva**

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

If you are using medicines containing any of the following:

- some medicines for fungal infections (e.g. ketoconazole);
- medicines to treat abnormal heart beat (e.g. dronedarone, quinidine, verapamil);
- other medicines to reduce blood clotting (e.g. heparin, clopidogrel or vitamin K antagonists such as warfarin, acenocoumarol, phenprocoumon or dabigatran, rivaroxaban, apixaban);
- antibiotic medicines (e.g. erythromycin, clarithromycin);
- medicines to prevent organ rejection after transplantation (e.g. ciclosporin);
- anti-inflammatory and pain-relieving medicines (e.g. naproxen or acetylsalicylic acid);
- antidepressant medicines called selective serotonin reuptake inhibitors or serotonin- norepinephrine reuptake inhibitors;

**If any of the above apply to you, tell your doctor** before taking Edoxaban Zentiva, because these

medicines may increase the effects of Edoxaban Zentiva and the chance of unwanted bleeding. Your doctor will decide, if you should be treated with Edoxaban Zentiva and if you should be kept under observation.

If you are taking any of the following:

- some medicines for treatment of epilepsy (e.g. phenytoin, carbamazepine, phenobarbital);
- St John's Wort, a herbal product used for anxiety and mild depression;
- rifampicin, an antibiotic medicine.

**If any of the above apply to you, tell your doctor** before taking Edoxaban Zentiva, because the effect of Edoxaban Zentiva may be reduced. Your doctor will decide if you should be treated with Edoxaban Zentiva and if you should be kept under observation.

### **Pregnancy and breast-feeding**

Do not take Edoxaban Zentiva if you are pregnant or breast-feeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking Edoxaban Zentiva. If you become pregnant while you are taking Edoxaban Zentiva, immediately tell your doctor, who will decide how you should be treated.

### **Driving and using machines**

Edoxaban Zentiva has no or negligible effects on your ability to drive or use machines.

## **3. How to take Edoxaban Zentiva**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **How much to take**

The recommended dose is one **60 mg** tablet once daily.

- if you have impaired kidney function, the dose may be reduced to one 30 mg tablet once daily by your doctor;
- if your body weight is 60 kg or lower, the recommended dose is one 30 mg tablet once daily;
- if your doctor has prescribed medicines known as P-gp inhibitors: ciclosporin, dronedarone, erythromycin, or ketoconazole, the recommended dose is one 30 mg tablet once daily.

### **How to take the tablet**

Swallow the tablet, preferably with water. Edoxaban Zentiva can be taken with or without food.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Edoxaban Zentiva. The tablet may be crushed and mixed with water or apple puree immediately before you take it. If necessary, your doctor may also give you the crushed Edoxaban Zentiva tablet through a tube via the nose (nasogastric tube) or a tube in the stomach (gastric feeding tube).

### **Your doctor may change your anticoagulant treatment as follows:**

*Changing from vitamin K antagonists (e.g. warfarin) to Edoxaban Zentiva*

Stop taking the vitamin K antagonist (e.g. warfarin). Your doctor will need to do blood measurements and will instruct you when to start taking Edoxaban Zentiva.

*Changing from non-VKA oral anticoagulants (dabigatran, rivaroxaban, or apixaban) to Edoxaban*

### *Zentiva*

Stop taking the previous medicines (e.g. dabigatran, rivaroxaban, or apixaban) and start Edoxaban Zentiva at the time of the next scheduled dose.

### *Changing from parenteral anticoagulants (e.g. heparin) to Edoxaban Zentiva*

Stop taking the anticoagulant (e.g. heparin) and start Edoxaban Zentiva at the time of the next scheduled anticoagulant dose.

### *Changing from Edoxaban Zentiva to vitamin K antagonists (e.g. warfarin)*

If you currently take 60 mg Edoxaban Zentiva:

Your doctor will tell you to reduce your dose of Edoxaban Zentiva to a 30 mg tablet once daily and to take it together with a vitamin K antagonist (e.g. warfarin). Your doctor will need to do blood measurements and will instruct you when to stop taking Edoxaban Zentiva.

If you currently take 30 mg (dose reduced) Edoxaban Zentiva:

Your doctor will tell you to reduce your dose of Edoxaban Zentiva to a 15 mg tablet once daily and to take it together with a vitamin K antagonist (e.g. warfarin). Your doctor will need to do blood measurements and will instruct you when to stop taking Edoxaban Zentiva.

### *Changing from Edoxaban Zentiva to non-VKA oral anticoagulants (dabigatran, rivaroxaban, or apixaban)*

Stop taking Edoxaban Zentiva and start the non-VKA anticoagulant (e.g. dabigatran, rivaroxaban, or apixaban) at the time of the next scheduled dose of Edoxaban Zentiva.

### *Changing from Edoxaban Zentiva to parenteral anticoagulants (e.g. heparin)*

Stop taking Edoxaban Zentiva and start the parenteral anticoagulant (e.g. heparin) at the time of the next scheduled dose of Edoxaban Zentiva.

### **Patients undergoing cardioversion:**

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take Edoxaban Zentiva at the times your doctor tells you to prevent blood clots in the brain and other blood vessels in your body.

### **If you take more Edoxaban Zentiva than you should**

Tell your doctor immediately if you have taken too many Edoxaban Zentiva tablets.

If you take more Edoxaban Zentiva than recommended, you may have an increased risk of bleeding.

### **If you forget to take Edoxaban Zentiva**

You should take the tablet immediately and then continue the following day with the once daily tablet as usual. Do not take a double dose on the same day to make up for a forgotten dose.

### **If you stop taking Edoxaban Zentiva**

Do not stop taking Edoxaban Zentiva without talking to your doctor first, because Edoxaban Zentiva treats and prevents serious conditions.

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.

Like other similar medicines (medicines to reduce blood clotting), Edoxaban Zentiva may cause bleeding which may potentially be life-threatening. In some cases the bleeding may not be obvious.

If you experience any bleeding event that does not stop by itself or if you experience signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling) consult your doctor immediately.

Your doctor may decide to keep you under closer observation or change your medicine.

**Overall list of possible side effects:**

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

- stomach ache;
- abnormal liver blood tests;
- bleeding from the skin or under the skin;
- anaemia (low levels of red blood cells);
- bleeding from the nose;
- bleeding from the vagina;
- rash;
- bleeding in the bowel;
- bleeding from the mouth and/or throat;
- blood found in your urine;
- bleeding following an injury (puncture);
- bleeding in the stomach;
- dizziness;
- feeling sick;
- headache;
- itching.

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

- bleeding in the eyes;
- bleeding from a surgical wound following an operation;
- blood in the spit when coughing;
- bleeding in the brain;
- other types of bleeding;
- reduced number of platelets in your blood (which can affect clotting);
- allergic reaction;
- hives.

**Rare** (may affect up to 1 in 1 000 people):

- bleeding in the muscles;
- bleeding in joints;
- bleeding in the abdomen;
- bleeding in the heart;
- bleeding inside the skull;
- bleeding following a surgical procedure;
- allergic shock;
- swelling of any part of the body due to allergic reaction.

**Not known** (frequency cannot be estimated from the available data)

- bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy).

### **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 Edoxaban 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 blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.  
Store in the original package in order to protect from moisture.

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 Edoxaban Zentiva contains**

- The active substance is edoxaban.  
Each film-coated tablet contains 15 mg edoxaban (as tosilate monohydrate).  
Each film-coated tablet contains 30 mg edoxaban (as tosilate monohydrate).  
Each film-coated tablet contains 60 mg edoxaban (as tosilate monohydrate).
- The other ingredients are:  
Tablet core: maize starch; maize starch, pregelatinized; crospovidone ; hydroxypropylcellulose (E463); magnesium stearate  
Tablet film coating: hypromellose , macrogol, talc  
Edoxaban Zentiva 15 mg contains additionally: iron oxide yellow (E172) and iron oxide red (E172).  
Edoxaban Zentiva 30 mg contains additionally: iron oxide red (E172).  
Edoxaban Zentiva 60 mg contains additionally: iron oxide yellow (E172).

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

Edoxaban Zentiva 15 mg: Red to brown round biconvex film-coated tablet with the diameter of approx. 6.5 mm.

Edoxaban Zentiva 30 mg: Pink round biconvex film-coated tablet with debossed "Z" on one side, with the diameter of approx. 8.0 mm.

Edoxaban Zentiva 60 mg: Yellow round biconvex film-coated tablet with the diameter of approx. 10.5 mm.

Packed into PVC/PVDC//Alu blisters.

Pack size:

Edoxaban Zentiva 15 mg: are available in blisters containing 10 film-coated tablets

Edoxaban Zentiva 30 mg are available in blisters containing 10, 14, 28, 30, 98 and 100 film-coated tablets

Edoxaban Zentiva 60 mg are available in blisters containing 10, 14, 28, 30, 60, 98 and 100 film-coated

**tablets**

Not all pack sizes may be marketed.

**Houder van de vergunning voor het in de handel brengen**

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

**Fabrikant**

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

of

Labormed-Pharma S.A.  
Bd. Theodor Pallady nr.  
44B, sector 3  
cod 032266 Boekarest  
Roemenië

**In het register ingeschreven onder:**

Edoxaban Zentiva 15 mg filmomhulde tabletten	RVG 132368
Edoxaban Zentiva 30 mg filmomhulde tabletten	RVG 132369
Edoxaban Zentiva 60 mg filmomhulde tabletten	RVG 132370

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Oostenrijk, Tsjechië, Denemarken, Estland, Finland, Duitsland, Hongarije, IJsland, Ierland, Italië, Letland, Litouwen, Nederland, Noorwegen, Portugal, Spanje, Zweden: Edoxaban Zentiva

**Deze bijsluiter is voor het laatst goedgekeurd in januari 2025.**