

Package leaflet: Information for the patient
Edoxaban Accord 15 mg film-coated tablets
Edoxaban Accord 30 mg film-coated tablets
Edoxaban Accord 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 Accord is and what it is used for
2. What you need to know before you take Edoxaban Accord
3. How to take Edoxaban Accord
4. Possible side effects
5. How to store Edoxaban Accord
6. Contents of the pack and other information

1. What Edoxaban Accord is and what it is used for

Edoxaban Accord 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 Accord 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 Accord

Do not take Edoxaban Accord

- 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 Accord ,

- if you have an increased risk of bleeding, as could be the case if you have any of the following conditions:
 - endstage 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 Accord 15 mg is only to be used when changing from Edoxaban Accord 30 mg to a vitamin K antagonist (e.g. warfarin) (see section 3. How to take Edoxaban Accord).

Take special care with Edoxaban Accord,

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

Children and adolescents

Edoxaban Accord is not recommended in children and adolescents under 18 years of age.

Other medicines and Edoxaban Accord

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

If you are taking 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 serotoninorepinephrine reuptake inhibitors;

If any of the above apply to you, tell your doctor before taking Edoxaban Accord , because these medicines may increase the effects of Edoxaban Accord and the chance of unwanted bleeding. Your doctor will decide, if you should be treated with Edoxaban Accord 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 Accord , because the effect of Edoxaban Accord may be reduced. Your doctor will decide if you should be treated with Edoxaban Accord and if you should be kept under observation.

Pregnancy and breast-feeding

Do not take Edoxaban Accord 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 Accord . If you become pregnant while you are taking Edoxaban Accord, immediately tell your doctor, who will decide how you should be treated.

Driving and using machines

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

Edoxaban Accord contains lactose

Edoxaban Accord contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Edoxaban Accord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially "sodium free".

3. How to take Edoxaban Accord

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 Accord can be taken with or without food.

[For 30 mg film-coated tablets only:] The tablet can be divided into equal doses.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Edoxaban Accord. 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 Accord tablet through a tube via the nose (nasogastric tube) or a tube in the stomach (gastric feeding tube) made of PVC with a bore of at least 16 French. Afterwards the tube should be flushed with 125 ml water.

Your doctor may change your anticoagulant treatment as follows:

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

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 Accord.

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

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

Changing from parenteral anticoagulants (e.g. heparin) to Edoxaban Accord

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

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

If you currently take 60 mg Edoxaban Accord :

Your doctor will tell you to reduce your dose of Edoxaban Accord 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 Accord .

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

Your doctor will tell you to reduce your dose of Edoxaban Accord 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 Accord .

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

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

Changing from Edoxaban Accord to parenteral anticoagulants (e.g. heparin)

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

Patients undergoing cardioversion:

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take Edoxaban Accord 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 Accord than you should

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

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

If you forget to take Edoxaban Accord

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 Accord

Do not stop taking Edoxaban Accord without talking to your doctor first, because Edoxaban Accord 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 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

HPRA Pharmacovigilance,

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Edoxaban Accord

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 on each blister or bottle 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 Edoxaban Accord contains

The active substance is edoxaban (as tosilate).

Edoxaban Accord 15 mg film-coated tablets

Each tablet contains 15 mg edoxaban (as tosilate).

Edoxaban Accord 30 mg film-coated tablets

Each tablet contains 30 mg edoxaban (as tosilate).

Edoxaban Accord 60 mg film-coated tablets

Each tablet contains 60 mg edoxaban (as tosilate).

The other ingredients are:

Edoxaban Accord 15 mg film-coated tablets

Tablet core: Lactose monohydrate (milled), sodium starch glycolate, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate.

Film coat: hypromellose, talc, macrogol (8000), titanium dioxide (E171), Iron oxide yellow (E172), Iron oxide red (E172).

Edoxaban Accord 30 mg film-coated tablets

Tablet core: Lactose monohydrate (milled), sodium starch glycolate, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate.

Film coat: hypromellose, talc, macrogol (8000), titanium dioxide (E171), Iron oxide red (E172).

Edoxaban Accord 60 mg film-coated tablets

Tablet core: Lactose monohydrate (milled), sodium starch glycolate, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate.

Film coat: hypromellose, talc, macrogol (8000), titanium dioxide (E171), Iron oxide yellow (E172).

What Edoxaban Accord looks like and contents of the pack

Edoxaban Accord 15 mg film-coated tablets are orange, round-shaped (approximately 6.7 mm diameter) and debossed with “15” on one side and “EDX” on the other side.

They come in blisters in cartons of 10 or 30 film-coated tablets.

Edoxaban Accord 30 mg film-coated tablets are pink, round-shaped (approximately 8.5 mm diameter) with breakline on one side and plain on the other side.

They come in blisters in cartons of 28, 30, 98 or 100 film-coated tablets.

Edoxaban Accord 60 mg film-coated tablets are yellow, round-shaped (approximately 10.5 mm diameter) and debossed with “60” on one side and “EDX” on the other side.

They come in blisters in cartons of 28, 30, 60, 98 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Limited
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857
Ireland

Manufacturer

Pharmadox Healthcare Ltd,
KW20A Kordin Industrial Park,
Paola, PLA 3000, Malta

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This medicinal product is authorized in the Member states of the EEA under following names:

Name of the member state	Name of the Medicine
Germany:	Edoxaban Accord 15 mg Filmtabletten Edoxaban Accord 30 mg Filmtabletten Edoxaban Accord 60 mg Filmtabletten
Estonia	Edoxaban Accord
Croatia	Edoksaban Accord 15 mg filmom obložene tablete; Edoksaban Accord 30 mg filmom obložene tablete; Edoksaban Accord 60 mg filmom obložene tablete
Hungary	Edoxaban Accord 15 mg filmtabletta; Edoxaban Accord 30 mg filmtabletta; Edoxaban Accord 60 mg filmtabletta
Iceland	Edoxaban Accord 15 mg filmcoated tablets; Edoxaban Accord 30 mg filmcoated tablets; Edoxaban Accord 60 mg filmcoated tablets

Lithuania	Edoxaban Accord 15 mg plėvele dengtos tabletės; Edoxaban Accord 30 mg plėvele dengtos tabletės; Edoxaban Accord 60 mg plėvele dengtos tabletės
Lativa	Edoxaban Accord 15 mg apvalkotās tabletes, Edoxaban Accord 30 mg apvalkotās tabletes; Edoxaban Accord 60 mg apvalkotās tabletes
Romania	Edoxaban Accord 15 mg comprimate filmate; Edoxaban Accord 30 mg comprimate filmate; Edoxaban Accord 60 mg comprimate filmate
Slovenia	Edoksaban Accord 15 mg filmsko obložene tablete; Edoksaban Accord 30 mg filmsko obložene tablete; Edoksaban Accord 60 mg filmsko obložene tablete
Slovakia	Edoxaban Accord 15 mg; Edoxaban Accord 30 mg; Edoxaban Accord 60 mg
Ireland	Edoxaban Accord 15 mg film-coated tablets; Edoxaban Accord 30 mg film-coated tablets; Edoxaban Accord 60 mg film-coated tablets

This leaflet was last revised in [10/2025]