

Package leaflet: information for the user

Edoxaban 15 mg film-coated tablets Edoxaban 30 mg film-coated tablets Edoxaban 60 mg film-coated tablets

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 film-coated tablets are and what they are used for
2. What you need to know before you take Edoxaban film-coated tablets
3. How to take Edoxaban film-coated tablets
4. Possible side effects
5. How to store Edoxaban film-coated tablets
6. Contents of the pack and other information

1. What Edoxaban film-coated tablets are and what they are used for

Edoxaban film-coated tablets contain the active substance edoxaban and belong 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 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 film-coated tablets

DO NOT take Edoxaban film-coated tablets

- 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 this medicine.

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

Take special care with this medicine.

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

Children and adolescents

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

Other medicines and Edoxaban film-coated tablets

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 aspirin);
- 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, because these medicines may increase the effects of edoxaban and the chance of unwanted bleeding. Your doctor will decide, if you should be treated with this medicine 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 this medicine, because the effect of edoxaban may be reduced. Your doctor will decide if you should be treated with this medicine and if you should be kept under observation.

Pregnancy and breast-feeding

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

Driving and using machines

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

3. How to take Edoxaban film-coated tablets

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 film-coated tablets can be taken with or without food.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take this medicine. 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 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 film-coated tablets

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 this medicine.

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

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

Changing from parenteral anticoagulants (e.g. heparin) to Edoxaban film-coated tablets

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

Changing from Edoxaban film-coated tablets to vitamin K antagonists (e.g. warfarin)

If you currently take **60 mg edoxaban**:

Your doctor will tell you to reduce your dose of edoxaban 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 this medicine.

If you currently take **30 mg (dose reduced) edoxaban**:

Your doctor will tell you to reduce your dose of edoxaban 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 this medicine.

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

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

Changing from Edoxaban film-coated tablets to parenteral anticoagulants (e.g. heparin)

Stop taking edoxaban and start the parenteral anticoagulant (e.g. heparin) at the time of the next scheduled dose of this medicine.

Patients undergoing cardioversion:

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take this medicine 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 film-coated tablets than you should

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

If you take more of this medicine than recommended, you may have an increased risk of bleeding.

If you forget to take Edoxaban film-coated tablets

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 film-coated tablets

Do not stop taking edoxaban without talking to your doctor first, because this medicine 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Edoxaban film-coated tablets

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 film-coated tablets contain

- The active substance is edoxaban (as tosilate monohydrate).

Edoxaban 15 mg film-coated tablets

Each tablet contains 15 mg edoxaban (as tosilate monohydrate).

Edoxaban 30 mg film-coated tablets

Each tablet contains 30 mg edoxaban (as tosilate monohydrate).

Edoxaban 60 mg film-coated tablets

Each tablet contains 60 mg edoxaban (as tosilate monohydrate).

The other ingredients are:

Edoxaban 15 mg film-coated tablets

Maltodextrin, Cellulose, microcrystalline, Sodium starch glycolate (type A), Cellulose, microcrystalline (low moisture), Crospovidone, Silica colloidal, anhydrous, Magnesium stearate (vegetable origin), Opadry TF 265F230006 Orange film-coat (consisting of: Hypromellose E464, Calcium Carbonate E170, Macrogol/PEG MW 8000, E1521, Talc E553b, iron oxide yellow E172, Iron oxide red E172, Black iron oxide E172), Carnauba wax

Edoxaban 30 mg film-coated tablets

Maltodextrin, Cellulose, microcrystalline, Sodium starch glycolate (type A), Cellulose, microcrystalline (low moisture), Crospovidone, Silica colloidal, anhydrous, Magnesium stearate (vegetable origin), Opadry TF 265F240040 Pink film-coat (consisting of: Hypromellose E464, Calcium Carbonate E170, Macrogol/PEG MW 8000, E1521, Talc E553b, iron oxide red E172, Carmine E120, Black iron oxide E172), Carnauba wax

Edoxaban 60 mg film-coated tablets

Maltodextrin, Cellulose, microcrystalline, Sodium starch glycolate (type A), Cellulose, microcrystalline (low moisture), Crospovidone, Silica colloidal, anhydrous, Magnesium stearate (vegetable origin), Opadry TF 265F220022 Yellow film-coat (consisting of: Hypromellose E464, Calcium Carbonate E170, Macrogol/PEG MW 8000, E1521, Talc E553b, iron oxide yellow E172, Black iron oxide E172, iron oxide red E172), Carnauba wax

What Edoxaban film-coated tablets look like and contents of the pack

Edoxaban 15 mg film-coated tablets are presented as orange, round, biconvex film-coated tablets with diameter of approximately 6 mm. Film coated tablets are supplied in PVC/PVdC/Al blisters or PVC/PVdC/Al unit-dose blisters consisting of 10 or 10x1 film-coated tablets, or HDPE bottles with a PP cap with integrated silica gel containing 100 or 500 film-coated tablets.

Edoxaban 30 mg film-coated tablets are presented as pink, round, biconvex film-coated tablets with diameter of approximately 8 mm. Film coated tablets are supplied in PVC/PVdC/Al blisters or PVC/PVdC/Al unit-dose blisters consisting of 10, 10x1, 14, 28, 28x1, 30, 50x1, 56, 60, 84, 90, 98, 100 or 100x1 film-coated tablets, or HDPE bottles with a PP cap with integrated silica gel containing 100 or 500 film-coated tablets.

Edoxaban 60 mg film-coated tablets are presented as yellow, round, biconvex, film-coated tablets with diameter of approximately 10 mm. Film coated tablets are supplied in PVC/PVdC/Al blisters or PVC/PVdC/Al unit-dose blisters consisting of 10, 10x1, 14, 28, 28x1, 30, 50x1, 56, 60, 84, 90, 98, 100 or 100x1 film-coated tablets, or HDPE bottles with a PP cap with integrated silica gel containing 100 or 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

STADA, Manchester Road, Lintwalle, Huddersfield, HD7 5QH, United Kingdom

Manufacturer

STADA Arzneimittel AG, Stadastraße 2 - 18, 61118, Bad Vilbel, Germany

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M2009 GB



Edoxaban 15 mg
film-coated tablets
Edoxaban 30 mg
film-coated tablets
Edoxaban 60 mg
film-coated tablets

M2009 GB



PATIENT ALERT CARD

Edoxaban

Please keep this card with you at all times.

Present it to your healthcare professional, pharmacist, surgeon or dentist before any medical treatment or intervention.

June 2025
STADA

ABOUT YOUR TREATMENT

You have been prescribed edoxaban, an anticoagulant medicine, which thins your blood and helps prevent you from suffering blood clots. It is important that you take your medicine exactly as instructed by your doctor.

- If you miss a dose, take it immediately and then continue the following day as normal – do not take double the prescribed dose in a single day.
- Do not start any other medications (including over the counter) without consulting your doctor.
- Do not stop taking edoxaban without consulting your doctor as this can increase your risk of developing a blood clot.
- Please read the Patient Information Leaflet found inside each pack of this medicine.

WHEN TO SEEK MEDICAL ADVICE

RISK OF BLEEDING

Taking an anticoagulant medicine such as edoxaban can increase your risk of bleeding. It is therefore important to be aware of the possible signs and symptoms of bleeding and to speak to your doctor **immediately** if you experience any of the following:

- Bruising or bleeding under the skin
- Blood in the urine
- Coughing up blood
- Vomiting blood or material that looks like ground coffee
- Nose bleeds or cuts that take a long time to stop bleeding
- Tar-coloured stools
- Dizziness or sudden headache
- Unexplained tiredness
- Abnormal vaginal bleeding, including heavier or prolonged menses

Please talk to your doctor if you experience any unusual symptoms.

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PATIENT INFORMATION

Patient name:

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Date of birth:

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In case of emergency, please contact:

Name:

.....

Phone no:

.....

TREATMENT INFORMATION

(To be completed by physician)

Edoxaban film-coated tablets has been prescribed at a once-daily dose of:mg

Started on: / (mm/yy)

Blood type:

Other medicines/conditions:

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PRESCRIBER INFORMATION

For more information or in case of emergency, please contact:

Physician's name:

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Phone number, practice stamp:

Signature of physician:

.....

INFORMATION FOR HEALTHCARE PROFESSIONALS

- Edoxaban is an oral anticoagulant factor Xa inhibitor.
- When an invasive procedure is required, edoxaban should be stopped at least 24 hours beforehand, and appropriate caution exercised.
- Edoxaban may increase the risk of bleeding. In case of clinically significant bleeding, stop treatment immediately.
- Coagulation tests such as international normalised ratio (INR), prothrombin time (PT), or activated partial thromboplastin time (aPTT) are not a useful measure of the effect of edoxaban. However, a calibrated anti-Factor Xa assay may help inform clinical decisions.

Please consult the Summary of Product Characteristics (SmPC) for more information.

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Produkt/Product: EDOXABAN FILM COATED TABLETS GB :PIL	
MOC Number: MOC-2025-2538	
STADA Mat.-Nr./Mat.-No.: M2009 GB	
STADA Art.-Nr./Art.-No: TBC	
Hersteller/Manufacturer: TBC	
Hersteller Art.-Nr./Manufacturer Art.-No.: TBC	
Format/Size: 626x305mm +1pack 253x70mm(not approved keyline)	
Schriftgröße/Font-size: 8pt - 18pt	
NTIN/GTIN: N/A	
PZN/EAN: N/A	
Pharma-Code: N/A	
Flattermarke/Collating mark: N/A	
1. Farbe/Colour: ■ Black	
2. Farbe/Colour:	
3. Farbe/Colour:	
4. Farbe/Colour:	
5. Farbe/Colour:	
6. Farbe/Colour:	
7. Farbe/Colour:	
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16. Farbe/Colour: ■ Keyline (Non-Printing)	
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