**Package leaflet: Information for the user**

**Edoxaban Teva 15 mg, filmomhulde tabletten**
**Edoxaban Teva 30 mg, filmomhulde tabletten**
**Edoxaban Teva 60 mg, filmomhulde tabletten**
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 [Product name] is and what it is used for

[Product name] 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.

[Product name] 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 [Product name]

**Do not take [Product name]**
- 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 [Product name],
- 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.

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

Take special care with [Product name],
- 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 [Product name] before and after the operation exactly at the times you have been told by your doctor. If possible, [Product name] should be stopped at least 24 hours before an operation. Your doctor will determine when to restart [Product name]. In emergency situations your physician will help determine the appropriate actions regarding [PRODUCT NAME].

**Children and adolescents**
[PRODUCT NAME] is not recommended in children and adolescents under 18 years of age.

**Other medicines and [Product name]**
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 serotonin-norepinephrine reuptake inhibitors;

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

**Pregnancy and breast-feeding**
Do not take [Product name] 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 [Product name]. If you become pregnant while you are taking [Product name], immediately tell your doctor, who will decide how you should be treated.

**Driving and using machines**
[Product name] has no or negligible effects on your ability to drive or use machines.

**[Product name] contains lactose and sodium**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per dose, 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. 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.
[Product name] can be taken with or without food.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take [PRODUCT NAME]. 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 [Product name] tablet through a tube via the nose (nasogactric 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 [Product name]*
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 [PRODUCT NAME].

*Changing from non-VKA oral anticoagulants (dabigatran, rivaroxaban, or apixaban) to [Product name]*
Stop taking the previous medicines (e.g. dabigatran, rivaroxaban, or apixaban) and start *[Product name]* at the time of the next scheduled dose.

*Changing from parenteral anticoagulants (e.g. heparin) to [Product name]*
Stop taking the anticoagulant (e.g. heparin) and start [Product name] at the time of the next scheduled anticoagulant dose.

*Changing from [Product name] to vitamin K antagonists (e.g. warfarin)*

If you currently take [Product name] 60 mg
Your doctor will tell you to reduce your dose *of [Product name]* 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 [Product name].
If you currently take [Product name] 30 mg (dose reduced):
Your doctor will tell you to reduce your dose of [Product name]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 [Product name].

*Changing from [Product name] to non-VKA oral anticoagulants (dabigatran, rivaroxaban, or apixaban)*
Stop taking [Product name] and start the non-VKA anticoagulant (e.g. dabigatran, rivaroxaban, or apixaban) at the time of the next scheduled dose of [Product name].

*Changing from [Product name] to parenteral anticoagulants (e.g. heparin)*
Stop taking [Product name] and start the parenteral anticoagulant (e.g. heparin) at the time of the next scheduled dose of [Product name].

**Patients undergoing cardioversion:**
If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take [PRODUCT NAME] 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 [Product name] than you should**
Tell your doctor immediately if you have taken too many [Product name] tablets.
If you take more [Product name] than recommended, you may have an increased risk of bleeding.

**If you forget to take [Product name]**
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 [Product name]**
Do not stop taking [PRODUCT NAME] without talking to your doctor first, because [PRODUCT NAME] 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), [Product name] 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 [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 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 [Product name] contains

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

[Product name] 15 mg film-coated tablets:
Each tablet contains edoxaban tosilate monohydrate equivalent to 15 mg edoxaban.

[Product name] 30 mg film-coated tablets
Each tablet contains edoxaban tosilate monohydrate equivalent to 30 mg edoxaban.

[Product name] 60 mg film-coated tablets
Each tablet contains edoxaban tosilate monohydrate equivalent to 60 mg edoxaban.

- The other ingredients are:

[Product name] 15 mg film-coated tablets
Tablet core: Lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, purified water, magnesium stearate
Film-coating: Hypromellose (E464), calcium carbonate (E170), macrogol (E1521), talc (E553b), iron oxide yellow (E172) and iron oxide red (E172).

[Product name] 30 mg film-coated tablets
Tablet core: Lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, purified water, magnesium stearate.
Film-coating: Hypromellose (E464), calcium carbonate (E170), macrogol (E1521), talc (E553b) and iron oxide red (E172).

[Product name] 60 mg film-coated tablets
Tablet core: Lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, purified water, magnesium stearate
Film-coating: Hypromellose (E464), calcium carbonate (E170), macrogol (E1521), talc (E553b) and iron oxide yellow (E172).

### What [PRODUCT NAME] looks like and contents of the pack

[Product name] 15 mg film-coated tablets are light orange, round-shaped (approximatively 6.4 mm diameter) and debossed with “TV” on one side and “15” on the other side.

[Product name] 30 mg film-coated tablets are pink, round-shaped (approximatively 8.5 mm diameter) and debossed with “TV” on one side and “30” on the other side.

[Product name] 60 mg film-coated tablets are yellow, round-shaped (approximatively 10.5 mm diameter) and debossed with “TV” on one side and “60” on the other side.

[Product name] is supplied in the following packsizes:

[Product name] 15 mg film-coated tablets are available in blisters containing 10 film-coated tablets, perforated unit-dose blisters containing 10 x 1 film-coated tablets or a bottle containing 100 film-coated tablets.

[Product name] 30 mg film-coated tablets are available in blisters containing 10, 28, 30, 100 and 105 film-coated tablets, perforated unit-dose blisters containing 10 x 1, 28 x 1, 30 x 1, 98 x 1 film-coated tablets or a bottle containing 100 and 120 film-coated tablets.

[Product name] 60 mg film-coated tablets are available in blisters containing 10, 28, 30, 100 and 105 film-coated tablets, perforated unit-dose blisters containing 10 x 1, 28 x 1, 30 x 1, 98 x 1 film-coated tablets or a bottle containing 100 and 120 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Teva Nederland B.V.
Swensweg 5
2031 GA Haarlem
Nederland

**Manufacturer**
TEVA Gyógyszergyár Zrt.
Pallagi út 13
4042 Debrecen
Hongarije

Actavis Ltd
BLB015, BLB016, Bulebel Industrial Estate
ZTN3000 Zejtun
Malta

**In het register ingeschreven onder:**
RVG 132834 Edoxaban Teva 15 mg, filmomhulde tabletten
RVG 132836 Edoxaban Teva 30 mg, filmomhulde tabletten
RVG 132837 Edoxaban Teva 60 mg. filmomhulde tabletten

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

| | |
|---|---|
| België | Edoxaban Teva 15 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten |
| | Edoxaban Teva 30 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten |
| | Edoxaban Teva 60 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten |
| Denemarken | Edoxaban Teva |
| Duitsland | Edoxaban-ratiopharm 15 mg Filmtabletten |
| | Edoxaban-ratiopharm 30 mg Filmtabletten |
| | Edoxaban-ratiopharm 60 mg Filmtabletten |
| Estland | Edoxaban Teva |
| Finland | Edoxaban ratiopharm 15 mg tabletti, kalvopäällysteinen |
| | Edoxaban ratiopharm 30 mg tabletti, kalvopäällysteinen |
| | Edoxaban ratiopharm 60 mg tabletti, kalvopäällysteinen |
| Hongarije | Edoxaban Teva 15 mg filmtabletta |
| | Edoxaban Teva 30 mg filmtabletta |
| | Edoxaban Teva 60 mg filmtabletta |
| Ierland | Edoxaban Teva 15 mg, 30 mg and 60 mg Film-coated Tablets |
| IJsland | Edoxaban Teva |
| Italië | EDOXABAN TEVA |
| Letland | Edoxaban Teva 30 mg apvalkotās tablets |
| | Edoxaban Teva 60 mg apvalkotās tabletes |
| Litouwen | Edoxaban Teva 30 mg plėvele dengtos tabletės |
| | Edoxaban Teva 60 mg plėvele dengtos tabletės |

| | |
|---|---|
| Luxemburg | Edoxaban Teva 15 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten<br>Edoxaban Teva 30 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten<br>Edoxaban Teva 60 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten |
| Nederland | Edoxaban Teva 15 mg, filmomhulde tabletten<br>Edoxaban Teva 30 mg, filmomhulde tabletten<br>Edoxaban Teva 60 mg, filmomhulde tabletten |
| Noorwegen | Edoxaban Teva |
| Oostenrijk | Edoxaban ratiopharm 15 mg Filmtabletten<br>Edoxaban ratiopharm 30 mg Filmtabletten<br>Edoxaban ratiopharm 60 mg Filmtabletten |
| Portugal | Edoxabano Teva |
| Roemenië | Edoxaban Teva 15 mg, 30 mg si 60 mg comprimate filmate |
| Slowakije | Edoxaban Teva 15 mg<br>Edoxaban Teva 30 mg<br>Edoxaban Teva 60 mg |
| Spanje | Edoxabán Teva 15 mg comprimidos recubiertos con película EFG<br>Edoxabán Teva 30 mg comprimidos recubiertos con película EFG<br>Edoxabán Teva 60 mg comprimidos recubiertos con película EFG |
| Tsjechië | Edoxaban Teva |
| Zweden | Edoxaban Teva |

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