TevaArt Ref: PID: 234792_s1 P: Edoxaban UK FC Tabs 15mg, 30mg & 60mg BUL | Version: 1 27 February 2025

UK & Ireland Artwork Department

Length: 380 mm
Width: 190 mm
Depth: -

Colours Used: Template BLACK

SKU (s): 32119921
32119932
32120025

Perforated: No

Fonts: Neo Sans For Teva.

Smallest Font Size: 10 pt
(excluding codes)

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Package leaflet: Information for the user

Edoxaban
15 mg, 30 mg and 60 mg Film-coated Tablets

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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 or nurse. 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 is and what it is 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 is and what it is used for

Edoxaban Film-coated Tablets contain 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 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)
- are actively bleeding
- 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)
- 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
- have a liver disease which leads to an increased risk of bleeding
- have uncontrolled high blood pressure
- are pregnant or breast feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking Edoxaban 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.
- 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 Edoxaban 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 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 Edoxaban.

In emergency situations your physician will help determine the appropriate actions regarding Edoxaban.

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

Other medicines and Edoxaban
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 heartbeat (e.g. dronedarone, quinidine or 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 or 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, 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 Edoxaban 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 or 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, because the effect of Edoxaban may be reduced. Your doctor will decide if you should be treated with Edoxaban 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 Edoxaban. If you become pregnant while you are taking Edoxaban, 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.

Important information about some of the ingredients of Edoxaban Film-coated Tablets
This medicine contains lactose 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 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 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. 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
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.

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

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

Changing from Edoxaban to vitamin K antagonists (e.g. warfarin)
If you are currently taking **Edoxaban 60 mg**
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 Edoxaban.

If you are currently taking **Edoxaban 30 mg (dose reduced)**
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 Edoxaban.

Changing from Edoxaban 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 Edoxaban.

Changing from Edoxaban 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 Edoxaban.

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

If you forget to take Edoxaban
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
Do not stop taking Edoxaban tablets without talking to your doctor first, because Edoxaban 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.

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 Website 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 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 contains
The active substance is edoxaban (as tosilate monohydrate).

Edoxaban 15 mg Film-coated Tablets
- Each tablet contains edoxaban tosilate monohydrate equivalent to 15 mg edoxaban.
- The other ingredients are:
  Tablet core: lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, purified water and magnesium stearate.
  Film-coating: hypromellose (E464), calcium carbonate (E170), macrogol (E1521), talc (E553b), iron oxide yellow (E172) and iron oxide red (E172).

Edoxaban 30 mg Film-coated Tablets
- Each tablet contains edoxaban tosilate monohydrate equivalent to 30 mg edoxaban.
- The other ingredients are:
  Tablet core: lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, purified water and magnesium stearate.
  Film-coating: hypromellose (E464), calcium carbonate (E170), macrogol (E1521), talc (E553b) and iron oxide red (E172).

Edoxaban 60 mg Film-coated Tablets
- Each tablet contains edoxaban tosilate monohydrate equivalent to 60 mg edoxaban.
- The other ingredients are:
  Tablet core: lactose monohydrate, croscarmellose sodium, hydroxypropyl cellulose, purified water and magnesium stearate.
  Film-coating: hypromellose (E464), calcium carbonate (E170), macrogol (E1521), talc (E553b) and iron oxide yellow (E172).

What Edoxaban looks like and contents of the pack
- Edoxaban 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.
- Available in blisters containing 10 film-coated tablets, perforated unit-dose blisters containing 10 film-coated tablets or a bottle containing 100 film-coated tablets.
- Edoxaban 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.
- Available in blisters containing 10, 28, 30, 100 and 105 film-coated tablets, perforated unit-dose blisters containing 10, 28, 30 and 98 film-coated tablets or a bottle containing 100 and 120 film-coated tablets.
- Edoxaban 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.
- Available in blisters containing 10, 28, 30, 100 and 105 film-coated tablets, perforated unit-dose blisters containing 10, 28, 30 and 98 film-coated tablets or a bottle containing 100 and 120 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer: Actavis Ltd., BLB015-016 Bulebel Industrial Estate, Zejtun, ZTN3000, Malta

This leaflet was last revised in March 2025.

PL 00289/2648, PL 00289/2649 and PL 00289/2650

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