PACKAGE LEAFLET

Package leaflet: Information for the user

Edoxaban Sandoz 15 mg, filmomhulde tabletten
Edoxaban Sandoz 30 mg, filmomhulde tabletten
Edoxaban Sandoz 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 [Nationally completed name] is and what it is used for

[Nationally completed 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.

[Nationally completed 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 [Nationally completed name]

Do not take [Nationally completed 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 [Nationally completed 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.

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

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

Children and adolescents

[Nationally completed name] is not recommended in children and adolescents under 18 years of age.

Other medicines and [Nationally completed 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 [Nationally completed name], because these medicines may increase the effects of [Nationally completed name] and the chance of unwanted bleeding. Your doctor will decide, if you should be treated with [Nationally completed 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 [Nationally completed name], because the effect of [Nationally completed name] may be reduced. Your doctor will decide if you should be treated with [Nationally completed name] and if you should be kept under observation.

Pregnancy and breast-feeding

Do not take [Nationally completed 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 [Nationally completed name]. If you become pregnant while you are taking [Nationally completed name], immediately tell your doctor, who will decide how you should be treated.

Driving and using machines

[Nationally completed name] has no or negligible effects on your ability to drive or use machines.

[Nationally completed name] contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

[Nationally completed name] contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed 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.
[Nationally completed 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 [Nationally completed 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 [Nationally completed name] 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 [Nationally completed 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 [Nationally completed name].

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

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

Changing from [Nationally completed name] to vitamin K antagonists (e.g. warfarin)
If you currently take 60 mg [Nationally completed name]:
Your doctor will tell you to reduce your dose of [Nationally completed 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 [Nationally completed name].
If you currently take 30 mg (dose reduced) [Nationally completed name]:
Your doctor will tell you to reduce your dose of [Nationally completed 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 [Nationally completed name].

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

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

Patients undergoing cardioversion:

If your abnormal heartbeat needs to be restored to normal by a procedure called cardioversion, take [Nationally completed 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 [Nationally completed name] than you should

Tell your doctor immediately if you have taken too many [Nationally completed name] tablets.
If you take more [Nationally completed name] than recommended, you may have an increased risk of bleeding.

If you forget to take [Nationally completed 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 [Nationally completed name]
Do not stop taking [Nationally completed name] without talking to your doctor first, because [Nationally completed 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), [Nationally completed 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 [Nationally completed 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 on each blister or bottle after EXP. The expiry date refers to the last day of that month.

Store below 25ºC.

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 [Nationally completed name] contains
- The active substance is edoxaban (as tosilate monohydrate).

[Nationally completed name] 15 mg film-coated tablets
Each tablet contains 15 mg edoxaban (as tosilate monohydrate).

[Nationally completed name] 30 mg film-coated tablets
Each tablet contains 30 mg edoxaban (as tosilate monohydrate).

[Nationally completed name] 60 mg film-coated tablets
Each tablet contains 60 mg edoxaban (as tosilate monohydrate).

- The other ingredients are:

[Nationally completed name] 15 mg film-coated tablets
Tablet core: Hydroxypropylcellulose (E463), lactose monohydrate, magnesium stearate (E470b), cellulose, microcrystalline (E460), croscarmellose sodium (E468)
Film coat: Hypromellose type 2910, 6.0 mPas. (E464), macrogol, titanium dioxide (E171), talc (E553b), iron oxide yellow (E172) and iron oxide red (E172).

[Nationally completed name] 30 mg film-coated tablets
Tablet core: Hydroxypropylcellulose (E463), lactose monohydrate, magnesium stearate (E470b), cellulose, microcrystalline (E460), croscarmellose sodium (E468)
Film coat: Hypromellose type 2910, 6.0 mPas. (E464), macrogol, titanium dioxide (E171), talc (E553b) and iron oxide red (E172).

[Nationally completed name] 60 mg film-coated tablets
Tablet core: Hydroxypropylcellulose (E463), lactose monohydrate, magnesium stearate (E470b), cellulose, microcrystalline (E460), croscarmellose sodium (E468)
Film coat: Hypromellose type 2910, 6.0 mPas. (E464), macrogol, titanium dioxide (E171), talc (E553b)

and iron oxide yellow (E172).

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] 15 mg film-coated tablets
Are light orange, round (diameter 6.7 mm), biconvex film-coated tablet (tablet) debossed with “EX 15” on one side.

[Nationally completed name] 30 mg film-coated tablets
Are light pink, round (diameter 8.6), biconvex film-coated tablet (tablet) debossed with “EX 30” on one side. Tablet size (average): diameter 8.6 mm.

[Nationally completed name] 60 mg film-coated tablets
Are light yellow, round (diameter 10.6 mm), biconvex film-coated tablet (tablet) debossed with “EX 60” on one side.

[Nationally completed name] are packed into PVC/Aluminium blisters, PVC/Aluminium perforated unit dose blisters or HDPE bottles with a polypropylene child resistant screw cap.

Blister pack sizes:

15 mg:
10 and 14 film-coated tablets in blisters in cartons.
10x1, 28x1 and 98x1 film-coated tablets in unit dose blisters in cartons.

30 and 60 mg:
10, 14, 28, 30, 50, 84, 98 and 100 film-coated tablets in blisters in cartons.
10x1, 28x1 and 98x1 film-coated tablets in unit dose blisters in cartons.

Blisters may or may not have imprinted calendar days.

Bottle pack sizes:
100, 120 and 250 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder
Sandoz B.V.
Hospitaaldreef 29
1315 RC Almere
Nederland

Fabrikant
Lek Pharmaceuticals, d.d.
Trimlini 2d
9220 Lendava
Slovenië

In het register ingeschreven onder:

Edoxaban Sandoz 15 mg, filmomhulde tabletten	RVG 131980
Edoxaban Sandoz 30 mg, filmomhulde tabletten	RVG 131982
Edoxaban Sandoz 60 mg, filmomhulde tabletten	RVG 131983

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Zweden	Edoxaban Sandoz
Belgie	Edoxaban Sandoz 15 mg filmomhulde tabletten
	Edoxaban Sandoz 30 mg filmomhulde tabletten
	Edoxaban Sandoz 60 mg filmomhulde tabletten
Tsjechie	Edoxaban Sandoz
Duitsland	Edoxaban HEXAL 15 mg Filmtabletten
	Edoxaban HEXAL 30 mg Filmtabletten
	Edoxaban HEXAL 60 mg Filmtabletten
Denemarken	Edoxaban Sandoz
Spanje	Edoxabán Sandoz 15 mg comprimidos recubiertos con película EFG
	Edoxabán Sandoz 30 mg comprimidosrecubiertos con película EFG
	Edoxabán Sandoz 60 mg comprimidos recubiertos con película EFG
Finland	Edoxaban Sandoz 15 mg tabletti, kalvopäällysteinen
	Edoxaban Sandoz 30 mg tabletti, kalvopäällysteinen
	Edoxaban Sandoz 60 mg tabletti, kalvopäällysteinen
Hongarije	Edoxaban Sandoz 30 mg filmtabletta
	Edoxaban Sandoz 60 mg filmtabletta
Ierland	Edoxaban tosylate monohydrate15 mg filmcoated Tablets
	Edoxaban tosylate monohydrate 30 mg film-coated tablets
Ijsland	Edoxaban Sandoz
Italie	Edoxaban Sandoz
Nederland	Edoxaban Sandoz 15 mg, filmomhulde tabletten
	Edoxaban Sandoz 30 mg, filmomhulde tabletten
	Edoxaban Sandoz 60 mg, filmomhulde tabletten
Noorwegen	Edoxaban Sandoz
Portugal	Edoxabano Sandoz
Slowakije	Edoxaban Sandoz 30 mg
	Edoxaban Sandoz 60 mg

Deze bijsluiter is voor het laatst goedgekeurd in januari 2025.