1.3.1 Package leaflet - Core

Bijsluiter: informatie voor de patiënt

Gledohib 15 mg filmomhulde tabletten
Gledohib 30 mg filmomhulde tabletten
Gledohib 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 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 [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.

For patients who are unable to swallow whole tablets, [Product name] may be crushed and mixed with water or apple puree and immediately administered orally (see section 5.2).
Alternatively, [Product name] may be crushed and suspended in at least 10 mL of water for one tablet, and administered through a nasogastric tube or gastric feeding tube made of different materials (polyvinyl chloride, silicone and polyurethane) within a range of 8-12 French diameter, after which it should be rinsed two times with at least 20 mL of water.
The suspension of crushed tablet, stored at room temperature, is stable for up to 4 hours after preparation.

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 60 mg [Product name]:
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 30 mg (dose reduced) [Product name]:
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].
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; bleeding from the mouth and/or throat; bleeding in the bowel; bleeding in the stomach; feeling sick;
- abnormal liver blood tests;
- bleeding from the skin or under the skin; rash; itching.
- anaemia (low levels of red blood cells);
- bleeding from the nose;
- bleeding from the vagina;
- blood found in your urine;
- bleeding following an injury (puncture);
- dizziness; headache.

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 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 [Product name] contains
- The active substance is edoxaban (as tosylate).

[Product name] 15 mg film-coated tablets

Each tablet contains edoxaban tosylate equivalent to 15 mg edoxaban.

[Product name] 30 mg film-coated tablets

Each tablet contains edoxaban tosylate equivalent to 30 mg edoxaban.

[Product name] 60 mg film-coated tablets

Each tablet contains edoxaban tosylate equivalent to 60 mg edoxaban.

- The other ingredients are:

  [Product name] 15 mg film-coated tablets
  Mannitol, hydroxypropylcellulose, crospovidone, Silica, colloidal anhydrous, magnesium stearate, (tablet core); Macrogol poly(vinyl alcohol) grafted copolymer (E1209), titanium dioxide (E171), Kaolin, heavy, Copovidone, Sodium laurilsulfate (see Section 2), Iron oxide yellow (E172), Iron oxide red (E172) (tablet coating).

  [Product name] 30 mg film-coated tablets
  Mannitol, hydroxypropylcellulose, crospovidone, Silica, colloidal anhydrous, magnesium stearate (tablet core); Macrogol poly(vinyl alcohol) grafted copolymer (E1209), titanium dioxide (E171), Kaolin, heavy, Copovidone , Sodium laurilsulfate (see Section 2), Iron oxide red (E172) (tablet coating).

  [Product name] 60 mg film-coated tablets
  Mannitol, hydroxypropylcellulose, crospovidone, Silica, colloidal anhydrous, magnesium stearate (tablet core); Macrogol poly(vinyl alcohol) grafted copolymer (E1209), titanium dioxide (E171), Kaolin, heavy, Copovidone , Sodium laurilsulfate (see Section 2), Iron oxide yellow (E172) (tablet coating).

What [Product name] looks like and contents of the pack
[Product name] 15 mg film-coated tablets are orange, round biconvex coated tablets (approximately 6 mm), debossed with “7X” on one side and “L” on the other side. Each carton contains 10, 28, 30, 98 or 100 film-coated tablets in blisters.

[Product name] 30 mg film-coated tablets are pink, round biconvex coated tablets (approximately 8 mm), debossed with “7X” on one side and “I” on the other side. Each carton contains 10, 28, 30, 98 or 100 film-coated tablets in blisters.

[Product name] 60 mg film-coated tablets are yellow, round biconvex coated tablets (approximately 10 mm), debossed with “7X” on one side and “H” on the other side. Each carton contains 10, 28, 30, 98 or 100 film-coated tablets in blisters.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen:
G.L. Pharma GmbH

Schlossplatz 1
8502 Lannach
Oostenrijk

Fabrikant:
Synthon Hispania S.L.
Calle De Castello 1
Sant Boi De Llobregat
08830 Barcelona
Spanje

Synthon B.V.
Microweg 22
Nijmegen
6545 CM Gelderland
Nederland

Synthon s.r.o.
Brnenska 597/32
Blansko
678 01 Jihomoravsky
Tsjechië

In het register ingeschreven onder:

Gledohib 15 mg, filmomhulde tabletten	RVG 133242
Gledohib 30 mg, filmomhulde tabletten	RVG 133243
Gledohib 60 mg, filmomhulde tabletten	RVG 133244

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland	Gledohib 15/30/60 mg, filmomhulde tabletten
Oostenrijk	Gledohib 15/30/60 mg-Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2025