

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pro-Edoxaban

Edoxaban Tablets

Read this carefully before you start taking **Pro-Edoxaban** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Pro-Edoxaban**.

What is Pro-Edoxaban used for?

Pro-Edoxaban is used in adults to:

- lower the risk of blood clots:
 - in the brain (stroke); and
 - in other blood vesselsin people who have atrial fibrillation (a type of irregular heartbeat).
- treat and prevent blood clots in the veins of the legs (deep vein thrombosis) or lungs (pulmonary embolism).

It is not known if Pro-Edoxaban is safe and effective in children.

How does Pro-Edoxaban work?

Pro-Edoxaban helps to reduce the risk of the formation of blood clots. Pro-Edoxaban blocks a protein called factor Xa. Factor Xa is involved in the natural formation of blood clots.

What are the ingredients in Pro-Edoxaban?

Medicinal ingredient: edoxaban tosylate monohydrate

Non-medicinal ingredients: croscarmellose sodium, ferric oxide red (30 mg and 15 mg tablets), ferric oxide yellow (60 mg and 15 mg tablets), hydroxypropyl cellulose, hypromellose 2910, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 8000, talc and titanium dioxide.

Pro-Edoxaban comes in the following dosage forms:

Tablets: 15 mg, 30 mg and 60 mg edoxaban (as edoxaban tosylate monohydrate).

Do not use Pro-Edoxaban if:

- You are at risk of serious bleeding. This may be because you:
 - had recent bleeding in the brain.
 - have active ulcers that are bleeding or were recently bleeding.

- You have liver and blood-clotting problems.
- You are pregnant or breast-feeding.
- You are already being treated with a medicine that stops your blood from clotting. Examples include: warfarin, dabigatran, or apixaban.
- You are allergic to:
 - edoxaban (active ingredient of Pro-Edoxaban) or
 - any of the other ingredients in Pro-Edoxaban.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Pro-Edoxaban. Talk about any health conditions or problems you may have, including if you:

- are at risk of bleeding. This may be because you have or have had:
 - bleeding disorders.
 - an ulcer in your stomach or bowel.
 - bleeding in your brain, stomach or bowel.
 - very high blood pressure, not controlled by medical treatment.
 - an operation on your brain, spinal column or eye.
- take any medicine that stops your blood from clotting.
- take aspirin, naproxen or ibuprofen (non-steroidal anti-inflammatory medications) on a regular basis.
- have liver or kidney problems.
- have blood in your urine
- have a blockage in an artery in your lungs.
- have a catheter that stays in your bladder.
- have a body weight below 132 lbs (60 kg).
- have a mechanical heart valve.
- have a heart problem as a result of rheumatic fever.
- had a recent injection into your spine such as an epidural.
- have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk in blood clots).
- plan to become pregnant or if you are pregnant. It is not known if Pro-Edoxaban will harm your unborn baby. Tell your healthcare professional right away if you become pregnant during treatment with Pro-Edoxaban.
- plan to breastfeed or if you are breastfeeding. It is not known if Pro-Edoxaban passes into your breast milk. You and your healthcare professional should decide if you will take Pro-Edoxaban or breastfeed. You should not do both.
- plan to have any surgery or a dental procedure. Tell all of your healthcare professionals and dentists that you are taking Pro-Edoxaban. They should talk to the healthcare professional who prescribed Pro-Edoxaban for you. This should be done before you have any surgery or dental procedure. You may need to stop and restart your treatment with Pro-Edoxaban.

Other warnings you should know about:

Risk of bleeding

- Taking Pro-Edoxaban may result in serious bleeding. You may bleed from your organs and you may die.
- Do not stop taking Pro-Edoxaban without first talking to your healthcare professional. This is important because blood clots may occur in the brain or in other blood vessels. This can cause death or severe disability.

Anticoagulant-Related Nephropathy (ARN): Some cases were reported in patients taking edoxaban tablets. It is a type of serious kidney damage caused by anticoagulant medicines. ARN causes bleeding in the kidneys, sometimes with the presence of blood in the urine. This leads to the kidneys being unable to function properly. Your healthcare professional may monitor the health of your kidneys during your treatment with Pro-Edoxaban. If you are experiencing symptoms of ARN during your treatment, tell your healthcare professional **right away**.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not use Pro-Edoxaban if you are taking any other anticoagulant (used to prevent blood clots) such as :

- unfractionated heparin (UFH), except if it is used to maintain a patent central venous or arterial catheter;
- enoxaparin and dalteparin, which are low molecular weight heparins (LMWH);
- fondaparinux, which is a heparin derivative;
- warfarin, dabigatran, apixaban or rivaroxaban, which are oral anticoagulants, except if you are switching therapy to or from Pro-Edoxaban .

The following may also interact with Pro-Edoxaban:

Taking Pro-Edoxaban with some other medicines may increase the risk of bleeding. Some of these medicines are:

- Cyclosporine (used to suppress the immune system).
- Dronedarone and quinidine (used to treat an irregular heartbeat).
- Erythromycin (used to treat bacterial infections).
- Ketoconazole (used to treat fungal infections).
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid and naproxen.
- Medicines that block the action of platelets, such as clopidogrel.
- Antidepressants called selective serotonin reuptake inhibitors (SSRIs), such as fluoxetine, or serotonin norepinephrine reuptake inhibitors (SNRIs), such as duloxetine.

How to take Pro-Edoxaban:

- You can take Pro-Edoxaban with or without food.
- If you are unable to swallow tablets whole, the tablet may be crushed and mixed with water or apple puree and taken right away.
- Take Pro-Edoxaban exactly as prescribed by your healthcare professional. Make sure to refill your prescription before you run out.
- **Do not stop taking Pro-Edoxaban without first talking with your healthcare professional. Stopping Pro-Edoxaban may increase your risk of blood clots.**
- If you plan to have surgery, or a medical or a dental procedure, tell your healthcare professional, including your dentist that you are taking Pro-Edoxaban. You may have to stop taking Pro-Edoxaban for a short time.
- Call your healthcare professional right away if you fall or injure yourself, especially if you hit your head. Your healthcare professional may need to examine you.

Usual dose:

- **To reduce the risk of blood clots in your brain (stroke) and other blood vessels**
 - 60 mg once a day
- **To treat and prevent blood clots in the veins of your legs or lungs**
 - 60 mg once a day.
 - You will receive Pro-Edoxaban after you have been given an injectable anticoagulant over 5-10 days.
- **Dose reductions**
 - The dose of Pro-Edoxaban is 30 mg once a day if you have one or more of the following:
 - Severe or moderate kidney problems
 - Low body weight of 60 kg (132 lbs) or less
 - You take P-gp inhibitors (type of medication) except for amiodarone and verapamil (types of P-gp inhibitor) while taking Pro-Edoxaban.

Overdose:

There are very few experiences of overdose with Pro-Edoxaban. Overdose with Pro-Edoxaban may lead to bleeding.

If you think you, or a person you are caring for, have taken too much Pro-Edoxaban, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of Pro-Edoxaban, take it as soon as you remember on the same day.
- Take your next dose at your usual time the next day.

- Do not take more than one dose of Pro-Edoxaban at the same time to make up for a missed dose.

What are possible side effects from using Pro-Edoxaban?

These are not all the possible side effects you may have when taking Pro-Edoxaban. If you experience any side effects not listed here, tell your healthcare professional.

Pro-Edoxaban affects blood clotting. Most side effects are related to bleeding. Pro-Edoxaban can cause bleeding that is serious and may lead to death.

Patients treated with Pro-Edoxaban may experience the following side effects:

- Rash or itchy skin

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath		✓	
Bleeding from nose	✓		
Bleeding in the stomach or bowel: dark stool (like tar), bright red blood in your toilet or on toilet tissue, vomiting blood		✓	
Bleeding from mouth or gums	✓		
Bruising and swelling		✓	
Blood in urine: pink or red urine		✓	
Vaginal bleeding: Increase in or more frequent menstrual bleeding, unexpected vaginal bleeding		✓	
UNCOMMON			
Bleeding into the brain: sudden, severe and unusual headache			✓
Bleeding in eyes		✓	
Coughing blood or blood stained sputum		✓	
Bleeding from the surgical wound, an injury or other medical procedure		✓	
Allergic reactions: rash, itching, hives, trouble swallowing or breathing (angioedema), throat tightening or constriction, swelling of the face, lips or tongue, sudden low blood pressure.			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Stevens-Johnson syndrome (SJS) (severe skin reactions): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands.			✓
RARE			
Bleeding into muscles: sudden pain or swelling in your muscles		✓	
Bleeding into a joint: stiff, sore, hot or painful joint		✓	
UNKNOWN FREQUENCY			
Abdominal pain	✓		
Anticoagulant-related nephropathy (ARN) (serious kidney damage caused by anticoagulant medicines): bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly		✓	
Dizziness	✓		
Headache	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store Pro-Edoxaban at room temperature between 15°C to 30°C
- Keep out of reach and sight of children.

If you want more information about Pro-Edoxaban:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this PATIENT MEDICATION INFORMATION by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by contacting Pro Doc Ltée : 1-800-361-8559, www.prodoc.qc.ca, medinfo@prodoc.qc.ca.

This leaflet was prepared by Pro Doc Ltée.

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