

**PART III: CONSUMER INFORMATION****PRO-APIXABAN  
Apixaban Tablets**

This leaflet is Part III of a three-part "Product Monograph" published when PRO-APIXABAN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-APIXABAN. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

PRO-APIXABAN is used in adults for the following conditions:

- **Knee or hip replacement surgery:** To prevent blood clots from forming after knee or hip replacement surgery.
- **Atrial fibrillation:** To reduce the risk of stroke (damage to part of the brain caused by an interruption of its blood supply), and systemic embolism (the sudden blocking of a blood vessel by a blood clot) in people who have a heart condition called *atrial fibrillation* (irregular heart beat).
- **Blood clots:** To treat deep vein thrombosis (blood clots in the veins of your legs) and pulmonary embolism (blood clots in the blood vessels of your lungs) and reduce the risk of them occurring again.

**What it does:**

PRO-APIXABAN belongs to a group of medicines called anticoagulants. This medicine helps to prevent blood clots from forming by blocking one of the molecules that causes blood clotting (known as Factor-Xa).

**When it should not be used:**

- you are aware of body lesions at risk of bleeding, including bleeding in the brain (stroke)
- you have certain types of abnormal bleeding such as recent bleeding of a stomach ulcer
- you have active bleeding, especially if you are bleeding excessively
- you have a severe liver disease which leads to increased risk of bleeding (hepatic coagulopathy)
- you are already taking medicines to prevent blood clots, e.g. warfarin (COUMADIN®), heparin, rivaroxaban (XARELTO®), dabigatran

(PRADAXA®), unless your physician has decided to switch you to PRO-APIXABAN

- you are also taking prasugrel (EFFIENT®) or ticagrelor (BRILINTA®)
- PRO-APIXABAN should not be used during pregnancy, since its effects on pregnancy and the unborn child are not known
- you are taking oral ketoconazole (a drug used to treat fungus infection)
- while epidural or spinal catheters are in place or within the first five hours after their removal. Your doctor will know what precautionary measures are required. PRO-APIXABAN is not recommended for patients receiving epidural pain control after surgery
- you have an artificial heart valve
- you are younger than 18 years old
- you are allergic (hypersensitive) to apixaban (active ingredient of PRO-APIXABAN) or any of the other ingredients of PRO-APIXABAN. The ingredients are listed in the "What the nonmedicinal ingredients are:" section of this leaflet

**What the medicinal ingredient is:**

Apixaban

**What the nonmedicinal ingredients are:**

Anhydrous lactose, croscarmellose sodium, magnesium stearate and microcrystalline cellulose.

Coating ingredients: Polyethylene glycol 8000, polyvinyl alcohol, talc, titanium dioxide, red ferric oxide (5 mg) and yellow iron oxide (2.5 mg).

**What dosage forms it comes in:**

Film-coated tablets in yellow colour, 2.5 mg.

Film-coated tablets in pink colour, 5 mg.

**WARNINGS AND PRECAUTIONS**

**Do not stop taking PRO-APIXABAN without first talking with your doctor. If you stop taking PRO-APIXABAN, blood clots may cause a stroke or other complications. This can be fatal or lead to severe disability.**

BEFORE you use PRO-APIXABAN talk to your doctor or pharmacist if you have any of the following:

- an increased risk of bleeding, such as:
  - **bleeding disorders**
  - **an active or a recent ulcer** of your stomach or bowel
  - **infection of the heart** (bacterial endocarditis)

- **recent bleeding in your brain** (hemorrhagic stroke)
- **very high blood pressure**, not controlled by medical treatment
- **a recent operation on your brain, spinal column or eye**
- **severe kidney disease**
- **mild or moderate liver disease**
- **have antiphospholipid syndrome**
- **a tube (catheter) inserted in your back**
- **had an injection into your spinal column within the previous 5 hours, such as an epidural**, for anaesthesia or pain relief.
- **had an operation for a hip fracture** because this medicine has not been studied for this condition.
- you are 75 years of age or older.

PRO-APIXABAN is not recommended in children and adolescents under 18 years of age.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

The effects of apixaban on pregnancy and the unborn child are not known. You should not take PRO-APIXABAN if you are pregnant. **Contact your doctor immediately** if you become pregnant while taking PRO-APIXABAN.

It is not known if apixaban passes into human breast milk. Ask your doctor or pharmacist for advice before taking PRO-APIXABAN while breast-feeding.

### **INTERACTIONS WITH THIS MEDICATION**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal supplements.

Some medicines may increase the effects of PRO-APIXABAN and some may decrease its effects. Your doctor will decide, if you should be treated with PRO-APIXABAN when taking these medicines and how closely you should be monitored.

### **Drugs that may interact with PRO-APIXABAN include:**

#### Medicines that may increase the effects of PRO-APIXABAN:

You are at an increased risk for bleeding if you take PRO-APIXABAN with one of these drugs:

- some **medicines for fungal infections** (e.g. ketoconazole, itraconazole, voriconazole and posaconazole)
- some **antiviral medicines for HIV / AIDS** (e.g. ritonavir)
- other **medicines that are used to reduce blood clotting** (e.g. enoxaparin, clopidogrel, prasugrel)
- **anti-inflammatory or pain medicines** (e.g. aspirin or naproxen)
- **medicines for high blood pressure or heart problems** (e.g. diltiazem)
- some **medicines for bacterial infections** (e.g. clarithromycin)
- **antidepressants/anti-anxiety** (SSRIs, SNRIs) (e.g. fluoxetine, citalopram, sertraline, escitalopram, venlafaxine, duloxetine)

#### Medicines that may reduce the effects of PRO-APIXABAN:

- **medicines to treat tuberculosis or other infections** (e.g. rifampin, rifampicin)
- **medicines to prevent epilepsy or seizures** (e.g. phenytoin, carbamazepine, or phenobarbital)
- **St John's Wort** (a herbal supplement used for depression)

### **PROPER USE OF THIS MEDICATION**

#### **PRO-APIXABAN can be taken with or without food.**

PRO-APIXABAN should be taken regularly, as prescribed, to ensure best results. All temporary discontinuations should be avoided, unless recommended by your physician.

#### Usual adult dose:

##### *Knee or hip replacement surgery:*

Take one 2.5 mg tablet twice daily, one in the morning and one in the evening. Take the tablet at the same time every day, preferably 12 hours apart. Swallow the tablet whole with a drink of water. **DO NOT** chew the tablet. **DO NOT** stop taking this medication without advice from the doctor.

Always take PRO-APIXABAN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **If you have trouble swallowing the tablet(s)**

Follow the steps below to crush the PRO-APIXABAN tablet(s). This will help make sure that all of the crushed tablet(s) will be taken.

**Steps**

- use a mortar and pestle or a similar device to crush the tablet(s)
- transfer the powder to a drinking glass or a small bowl
- when using water:
  - add a small amount of water (30 mL) to the mortar and pestle/device and stir
  - transfer the water to the drinking glass
  - mix the powder with the water and drink right away.
  - rinse the glass with a small amount of water and drink right away
- when using apple sauce:
  - mix the powder with a small amount of apple sauce (30 g) in a small bowl and eat with a spoon right away
  - add a small amount of water (30 mL) to the mortar and pestle/device and stir
  - transfer the water to the bowl and drink right away
  - rinse the bowl and the spoon with a small amount of water and drink right away.

**Length of treatment**

After major **hip** operation you will usually take the tablets for up to 38 days.

After major **knee** operation you will usually take the tablets for up to 14 days.

Do not stop taking PRO-APIXABAN without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early.

*Atrial fibrillation (AF):*

For most patients with AF, the recommended dose of PRO-APIXABAN is 5 mg taken orally twice daily.

Depending on your age, weight or kidney function, your doctor may prescribe 2.5 mg twice daily.

If you are currently taking warfarin (another oral anticoagulant) or receive anticoagulant treatment given by injection, and your doctor has decided PRO-APIXABAN is appropriate for you, make sure you ask your doctor when and how best to switch and start taking PRO-APIXABAN.

If you have atrial fibrillation and stop taking PRO-APIXABAN without talking to your doctor, you are at risk of suffering from a stroke or other complications due to blood clot formation, which can be fatal or lead to severe disability.

*Treatment and prevention of blood clots in the veins of your legs or lungs:*

Take 10 mg twice daily (two 5 mg tablets in the morning and two 5 mg tablets in the evening) for 7 days. For treatment after 7 days, take 5 mg twice daily (one 5 mg tablet in the morning and one 5 mg tablet in the evening).

After a minimum of 6 months of treatment, your doctor may prescribe PRO-APIXABAN 2.5 mg twice daily (one 2.5 mg tablet in the morning and one 2.5 mg tablet in the evening).

**Length of treatment**

This is long-term treatment and you should continue to take PRO-APIXABAN until your doctor says otherwise.

**Overdose:**

**Tell your doctor immediately** if you have taken more than the prescribed dose of PRO-APIXABAN.

You may have an increased risk of bleeding. If bleeding occurs, surgery or blood transfusions may be required.

If you think you have taken too much PRO-APIXABAN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you have missed a dose, take the medicine as soon as you remember and continue with your remaining daily dose of PRO-APIXABAN; then carry on taking one tablet, twice a day as normal.

Do not take a double dose to make up for a forgotten tablet of PRO-APIXABAN.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, PRO-APIXABAN can cause side effects, although not everybody gets them.

**Tell your doctor or pharmacist** if you experience any of the following symptoms after taking this medicine.

Like other similar medicines (anticoagulants), PRO-APIXABAN may cause bleedings which could possibly lead to anemia (a low blood cell count which may cause tiredness or paleness). In some cases this bleeding may not be obvious. Nausea (feeling sick) is also a common side effect.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
<b>Unknown frequency</b>	<b>Allergic Reaction:</b> Rash, hives, swelling of the face, lips, tongue, or throat, difficulty swallowing or breathing			✓
<b>Common</b>	<b>Anemia:</b> fatigue, loss of energy, weakness, shortness of breath		✓	
	Blood in the urine (that stains the urine pink or red)		✓	
	Bruising and swelling		✓	
	Bleeding: – in your eyes – from your gums and blood in your spit when coughing – from your rectum – abnormally heavy or long menstrual bleeding		✓	

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
<b>Uncommon</b>	Bleeding after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision		✓	
	Bleeding in your stomach, bowel or blood in the stool		✓	
	Bleeding from your nose		✓	
	<b>Liver Disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	<b>Low Blood Pressure:</b> dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up	✓		
<b>Rare</b>	Bleeding: – into a muscle		✓	

You should be aware that prescription medicines carry some risks and that all possible risks may not be known at this stage.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

***This is not a complete list of side effects. For any unexpected effects while taking PRO-APIXABAN, contact your doctor or pharmacist.***

**HOW TO STORE IT**

Store at room temperature (15°C to 30°C).

Keep out of the reach and sight of children.

Do not use PRO-APIXABAN after the expiry date which is stated on the carton, the blister, or on the bottle after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 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.*

#### MORE INFORMATION

##### If you want more information about PRO-APIXABAN:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>). Or by contacting Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca)

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