

PART III: CONSUMER INFORMATION

P^rXARELTO[®]
rivaroxaban tablets

This leaflet is Part 3 of a three-part "Product Monograph" published when XARELTO was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XARELTO. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

XARELTO is used for:

- **Prevention of blood clots after major hip or knee surgery**
- **Prevention of blood clots in your brain (stroke) and in other blood vessels in your body if you have atrial fibrillation**
- **Treatment and prevention of blood clots in the veins of your legs or lungs**

Blood clots could dislodge and travel to the lungs causing serious health risks. Your doctor has prescribed this medication for you because after such an operation you are at an increased risk of getting blood clots.

Your doctor has prescribed this medication for you because you have a form of irregular heart rhythm called atrial fibrillation which can lead to blood clots forming and increases your risk of a stroke.

Your doctor has prescribed this medication for you because you have blood clots in the veins of your legs. This makes you at risk of a blood clot dislodging and traveling to the lungs causing serious health risks.

What it does:

XARELTO is an anticoagulant. It helps prevent blood clots from forming by directly blocking the activity of clotting Factor-Xa.

When it should not be used:

- if you have severe liver disease which leads to an increased risk of bleeding
- if you have active bleeding, especially if you are bleeding excessively
- if you are aware of body wounds or injuries at risk of bleeding, including bleeding in the brain or bleeding in your stomach or gut
- if you are taking certain oral medications to treat fungal infections or HIV/AIDS, such as NIZORAL[®] (ketoconazole) or NORVIR[®] (ritonavir)
- if you are taking other anticoagulants (blood thinners) such as warfarin, apixaban, dabigatran, heparin or low molecular weight heparin (LMWH) including enoxaparin, dalteparin or heparin derivatives, such as fondaparinux
- if you are pregnant or breastfeeding
- if you are allergic (hypersensitive) to rivaroxaban (active ingredient of XARELTO) or any of the other ingredients of XARELTO. The ingredients are listed in the "**What the nonmedicinal ingredients are**" section of this leaflet

What the medicinal ingredient is:

rivaroxaban

What the nonmedicinal ingredients are:

cellulose microcrystalline, croscarmellose sodium, ferric oxide red, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, sodium lauryl sulfate, titanium dioxide

What dosage forms it comes in:

Film-coated tablets, 10 mg, 15 mg and 20 mg.

For the treatment of a blood clot in the veins of your legs or lungs, a Starter Pack is available for the first 28 days of therapy. The Starter Pack includes 15 mg and 20 mg tablets.

WARNINGS AND PRECAUTIONS

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

As with other blood thinners, taking XARELTO may result in serious or life-threatening bleeding from any site, including internal organs.

Take special care when using XARELTO:

- if you have an increased risk of bleeding, as could be the case with conditions such as
 - bleeding disorders

- very high blood pressure, not controlled by medical treatment
- active ulcer or a recent ulcer of your stomach or bowel
- a problem with the blood vessels in the back of your eyes (retinopathy)
- recent bleeding in your brain (stroke, intracranial or intracerebral bleeding)
- problems with the blood vessels in your brain or spinal column
- a recent operation on your brain, spinal column or eye
- a chronic disease of the airways in your lungs causing widening, damage and scarring (bronchiectasis), or a history of bleeding into your lungs
- if you are older than 75 years of age

For the treatment and prevention of blood clots in the veins of your legs or lungs, XARELTO is not recommended if your doctor determines that:

- you are not able to maintain an adequate blood pressure
- you are taking drugs to break down your blood clots
- you have been scheduled for emergency surgical removal of blood clots from your lung

Tell your doctor before you take XARELTO, if any of these apply to you. Your doctor may decide to keep you under closer observation.

- If you are having surgery for any reason including an operation that involves a catheter or injection into your spinal column (eg, for epidural or spinal anesthesia or pain reduction):
 - it is very important to take XARELTO before and after the procedure/injection or removal of a catheter exactly at the times you have been told by your doctor
 - tell your doctor immediately if you get numbness or weakness of your legs, or problems with your bowel or bladder after the end of anesthesia, because urgent care is necessary

Lactose is a nonmedicinal ingredient in XARELTO. Do not take XARELTO if a doctor has told you that you have one of the following rare hereditary diseases:

- Galactose intolerance
- Lapp lactase deficiency
- Glucose-galactose malabsorption

XARELTO is not recommended if you have severe kidney disease. Your doctor will know how to determine your kidney function.

XARELTO is not recommended if you have an artificial heart valve.

XARELTO is not recommended in children younger than 18 years old.

Pregnancy and breastfeeding

If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking XARELTO. If you become pregnant while you are taking XARELTO, immediately tell your doctor, who will decide how you should be treated.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking:

- anticoagulants (blood thinners) such as warfarin, heparin or low molecular weight heparin (LMWH) including enoxaparin, fondaparinux, bivalirudin, apixaban, dabigatran, or anti-platelet agents, such as clopidogrel, ticlopidine, prasugrel, ticagrelor
- oral medications to treat fungal infections such as ketoconazole, itraconazole, posaconazole
- medications for HIV/AIDS such as ritonavir [NORVIR®] and lopinavir/ritonavir [KALETRA®]
- anti-inflammatory and pain relieving medicines including non-steroidal anti-inflammatory drugs (NSAIDs) (eg, naproxen [NAPROSYN®] or acetylsalicylic acid [ASPIRIN®])
- some antibiotics such as clarithromycin
- rifampicin
- anticonvulsants (to control seizures or fits) such as phenytoin, carbamazepine, phenobarbital

If you take XARELTO with NSAIDs or antiplatelet agents such as ASA or clopidogrel you are at an increased risk for bleeding. The use of XARELTO with prasugrel or ticagrelor is not recommended.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medication, including medications obtained without a prescription as well as vitamins and herbal supplements, such as St. John's Wort. Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

PROPER USE OF THIS MEDICATION

If you are currently taking warfarin (another blood thinner taken by mouth) or receive other anticoagulant treatment given by injection, and your doctor has decided XARELTO is appropriate for you, make sure you ask your doctor exactly when and how best to switch and start taking XARELTO.

Always follow your doctor’s instructions. Do not stop taking XARELTO without talking to your doctor first, because XARELTO helps prevent the development of blood clots.

Swallow the tablet preferably with water. Try to take the tablet at the same time every day to help you to remember it.

Prevention of blood clots after major hip or knee surgery

Usual dose: 10 mg once a day with or without food.

Take the first tablet 6 to 10 hours after your operation. Then take a tablet every day until your doctor tells you to stop.

If you have had a major hip operation, you will usually take XARELTO for 35 days.

If you have had a major knee operation, you will usually take XARELTO for 14 days.

Prevention of blood clots in your brain (stroke) and in other blood vessels in your body if you have atrial fibrillation

Usual dose: 20 mg once a day with food.

To be sure that you get the full benefit from XARELTO, it is important to take the 20 mg tablets with food.

If your kidneys are not working properly, your doctor may prescribe 15 mg once a day with food.

To be sure that you get the full benefit from XARELTO, it is important to take the 15 mg tablets with food.

This is long-term treatment and you should continue to take XARELTO until your physician says otherwise.

The recommended maximum daily dose is 20 mg.

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

Day 1 to 21: 15 mg, 1 tablet twice a day (one 15 mg tablet in the morning and one in the evening) with food.

From Day 22 onwards: 20 mg, 1 tablet once a day with food.

This is long-term treatment and you should continue to take XARELTO until your physician says otherwise.

Swallow the tablet preferably with water.

Overdose

Taking too much XARELTO increases the risk of bleeding.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose

If you are prescribed XARELTO 10 mg, 15 mg or 20 mg **once** a day and you have missed a dose, take it as soon as you remember. Take the next tablet on the following day at the usual time and then carry on taking a tablet once a day as normal. Do not take a double dose to make up for a forgotten tablet.

If you are prescribed XARELTO 15 mg **twice** a day and you have missed a dose, take it as soon as you remember. Do not take more than two 15 mg tablets on one day. If you forget to take a dose you can take two 15 mg tablets at the same time to get a total of two tablets (30 mg) on one day. On the following day you should carry on taking one 15 mg tablet twice a day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, XARELTO can cause side effects, although not everybody gets them.

As XARELTO acts on the blood clotting system, most side effects are related to signs of bruising or bleeding. In some cases bleeding may not be obvious, such as unexplained swelling.

Patients treated with XARELTO may also experience the following side effects:

Nausea, vomiting, stomach ache, constipation, diarrhea, indigestion, and decreased general strength and energy.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Bleeding from the surgical wound, an injury or other medical procedure		✓	
	Unexpected bruising		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
	Reduction in red blood cells which can make your skin pale and cause weakness, tiredness, dizziness, headache, breathlessness, unusually fast heartbeat, or chest pain		✓	
	Bleeding into the eye	✓		
	Bleeding from stomach (blood in vomit) or bowel (blood in stools/black stools)		✓	
	Bleeding from hemorrhoids	✓		
	Bleeding under the skin	✓		
	Blood in your urine, (red/pink tinge to urine)		✓	
	Genital bleeding in post menopausal women		✓	
	Increased or more frequent menstrual bleeding	✓		
	Localized swelling		✓	
	Nose bleed lasting more than 5 minutes		✓	
	Pain or swelling in your limbs		✓	
	Low blood pressure (lightheaded-ness, dizziness, and/or fainting)		✓	
	Fever		✓	
	Unusually fast heartbeat		✓	
	Itchy skin or rash		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/ Effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
	Bleeding gums for longer than 5 minutes when you brush your teeth		✓	
Un-common	Bleeding into the brain (sudden, severe and unusual headache)			✓
	Coughing up blood		✓	
	Bleeding into a joint (stiff, sore, hot or painful joint)		✓	
	Oozing from the surgical wound		✓	
	Decreased urine output	✓		
Rare	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, and difficulty swallowing or breathing			✓
Unknown	Compartment Syndrome: increased pressure within legs or arms after a bleed, with pain, swelling, numbness or paralysis		✓	
	Agranulocytosis [frequent infection with fever, sore throat, mouth ulcers (sign of decreased white blood cells)]		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/ Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Stevens-Johnson syndrome: Severe skin rash with 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			✓

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

HOW TO STORE IT

Keep at room temperature (15°C-30°C).

Keep out of the reach and sight of children.

Do not use XARELTO after the expiry date which is stated on the bottle and on each blister 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 throw away medicines you no longer use. These measures will help to protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online: www.healthcanada.gc.ca/medeffect

Call toll-free at: 866-234-2345

Complete a Canada Vigilance Reporting Form and:

Fax toll-free to: 866-678-6789

Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada website at: www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Inc. at 1-800-265-7382.

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the manufacturer at the above-mentioned phone number.

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