

MEDICATION GUIDE
XARELTO® (zah-REL-toe)
(rivaroxaban)
tablets

Read this Medication Guide before you start taking XARELTO and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about XARELTO?

- **For people taking XARELTO for atrial fibrillation:**

People with atrial fibrillation (an irregular heart beat) are at an increased risk of forming a blood clot in the heart, which can travel to the brain, causing a stroke, or to other parts of the body. XARELTO lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking XARELTO, you may have increased risk of forming a clot in your blood.

Do not stop taking XARELTO without talking to the doctor who prescribes it for you. Stopping XARELTO increases your risk of having a stroke.

If you have to stop taking XARELTO, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

- **XARELTO can cause bleeding** which can be serious, and rarely may lead to death. This is because XARELTO is a blood thinner medicine that reduces blood clotting. While you take XARELTO you are likely to bruise more easily and it may take longer for bleeding to stop.

You may have a higher risk of bleeding if you take XARELTO and take other medicines that increase your risk of bleeding, including:

- aspirin or aspirin containing products
- non-steroidal anti-inflammatory drugs (NSAIDs)
- warfarin sodium (Coumadin®, Jantoven®)
- any medicine that contains heparin
- clopidogrel (Plavix®)
- other medicines to prevent or treat blood clots

Tell your doctor if you take any of these medicines. Ask your doctor or pharmacist if you are not sure if your medicine is one listed above.

Call your doctor or get medical help right away if you develop any of these signs or symptoms of bleeding:

- unexpected bleeding or bleeding that lasts a long time, such as:
 - nose bleeds that happen often
 - unusual bleeding from the gums
 - menstrual bleeding that is heavier than normal or vaginal bleeding

- bleeding that is severe or you cannot control
 - red, pink or brown urine
 - bright red or black stools (looks like tar)
 - cough up blood or blood clots
 - vomit blood or your vomit looks like “coffee grounds”
 - headaches, feeling dizzy or weak
 - pain, swelling, or new drainage at wound sites
- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like XARELTO, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot than can cause long-term or permanent loss of the ability to move (paralysis). Your risk of developing a spinal or epidural blood clot is higher if:
 - a thin tube called an epidural catheter is placed in your back to give you certain medicine.
 - you take NSAIDs or a medicine to prevent blood from clotting
 - you have a history of difficult or repeated epidural or spinal punctures
 - you have a history of problems with your spine or have had surgery on your spine.

If you take XARELTO and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots. Tell your doctor right away if you have tingling, numbness, or muscle weakness, especially in your legs and feet.

See “What are the possible side effects of XARELTO?” for more information about side effects.

What is XARELTO?

- XARELTO is a prescription medicine used to:
 - reduce the risk of stroke and blood clots in people who have a medical condition called atrial fibrillation. With atrial fibrillation, part of the heart does not beat the way it should. This can lead to the formation of blood clots, which can travel to the brain, causing a stroke, or to other parts of the body.
 - treat blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) and reduce the risk of them occurring again.
 - reduce the risk of forming a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery.

It is not known if XARELTO is safe and effective in children.

Who should not take XARELTO?

Do not take XARELTO if you:

- currently have certain types of abnormal bleeding. Talk to your doctor before taking XARELTO if you currently have unusual bleeding.
- are allergic to rivaroxaban or any of the ingredients in XARELTO. See the end of this leaflet for a complete list of ingredients in XARELTO.

What should I tell my doctor before taking XARELTO?

Before you take XARELTO, tell your doctor if you:

- have ever had bleeding problems
- have liver or kidney problems
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if XARELTO will harm your unborn baby. Tell your doctor right away if you become pregnant while taking XARELTO. If you take XARELTO during pregnancy tell your doctor right away if you have any bleeding or symptoms of blood loss.
- are breastfeeding or plan to breastfeed. It is not known if XARELTO passes into your breast milk. You and your doctor should decide if you will take XARELTO or breastfeed.

Tell all of your doctors and dentists that you are taking XARELTO. They should talk to the doctor who prescribed XARELTO for you before you have any surgery, medical or dental procedure.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some of your other medicines may affect the way XARELTO works. Certain medicines may increase your risk of bleeding. See **“What is the most important information I should know about XARELTO?”**

Especially tell your doctor if you take:

- ketoconazole (Nizoral[®])
- itraconazole (Onmel[™], Sporanox[®])
- ritonavir (Norvir[®])
- lopinavir/ritonavir (Kaletra[®])
- indinavir (Crixivan[®])
- carbamazepine (Carbatrol[®], Equetro[®], Tegretol[®], Tegretol[®]-XR, Teril[™], Eptol[®])
- phenytoin (Dilantin-125[®], Dilantin[®])
- phenobarbital (Solfoton[™])
- rifampin (Rifater[®], Rifamate[®], Rimactane[®], Rifadin[®])
- St. John's wort (Hypericum perforatum)

Ask your doctor if you are not sure if your medicine is one listed above.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take XARELTO?

- Take XARELTO exactly as prescribed by your doctor.
- Do not change your dose or stop taking XARELTO unless your doctor tells you to.
- Your doctor will tell you how much XARELTO to take and when to take it.
- Your doctor may change your dose if needed.
- If you take XARELTO for:
 - **atrial fibrillation:**
 - Take XARELTO 1 time a day with your evening meal.
 - If you miss a dose of XARELTO, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
 - **blood clots in the veins of your legs or lungs:**
 - Take XARELTO once or twice a day as prescribed by your doctor.
 - Take XARELTO with food at the same time each day.
 - If you miss a dose of XARELTO:
 - **and take XARELTO 2 times a day:** Take XARELTO as soon as you remember on the same day. You may take 2 doses at the same time to make up for the missed dose. Take your next dose at your regularly scheduled time.
 - **and take XARELTO 1 time a day:** Take XARELTO as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
 - **hip or knee replacement surgery:**
 - Take XARELTO 1 time a day with or without food.
 - If you miss a dose of XARELTO, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take XARELTO.
- Your doctor will decide how long you should take XARELTO. Do not stop taking XARELTO without talking with your doctor first.
- Your doctor may stop XARELTO for a short time before any surgery, medical or dental procedure. Your doctor will tell you when to start taking XARELTO again after your surgery or procedure.

- Do not run out of XARELTO. Refill your prescription of XARELTO before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have XARELTO available to avoid missing any doses.
- If you take too much XARELTO, go to the nearest hospital emergency room or call your doctor right away.

What are the possible side effects of XARELTO?

- See **“What is the most important information I should know about XARELTO?”**

Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XARELTO?

- Store XARELTO at room temperature between 68°F to 77°F (20° to 25° C).

Keep XARELTO and all medicines out of the reach of children.

General information about XARELTO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use XARELTO for a condition for which it was not prescribed. Do not give XARELTO to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about XARELTO. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about XARELTO that is written for health professionals.

For more information call 1-800-526-7736 or go to www.XARELTO-US.com.

What are the ingredients in XARELTO?

Active ingredient: rivaroxaban

Inactive ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate.

The proprietary film coating mixture for XARELTO 10 mg tablets is Opadry® Pink contains: ferric oxide red, hypromellose, polyethylene glycol 3350, and titanium dioxide.

The proprietary film coating mixture for XARELTO 15 mg tablets is Opadry® Red, contains: ferric oxide red, hypromellose, polyethylene glycol 3350, and titanium dioxide.

The proprietary film coating mixture for XARELTO 20 mg tablets is Opadry® II Dark Red, contains: ferric oxide red, polyethylene glycol 3350, polyvinyl alcohol (partially hydrolyzed), talc, and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Finished Product Manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Licensed from:
Bayer HealthCare AG
51368 Leverkusen, Germany

Revised: March 2013

© Janssen Pharmaceuticals, Inc. 2011

Trademarks are property of their respective owners.