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 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®)
• selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
• 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 that 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 back pain, tingling, numbness, muscle weakness (especially in your legs and feet), loss of control of the bowels or bladder (incontinence).

• XARELTO is not for patients with artificial heart valves.

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®)
- indinavir (Crixivan®)
- carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol-XR, Teril™, Epitol®)
- phenytoin (Dilantin-125®, Dilantin®)
- lopinavir/ritonavir (Kaletra®)
- itraconazole (Onmel™, Sporanox®)
- phenobarbital (Solfoton™)
- ketoconazole (Nizoral®)
- St. John's wort (Hypericum perforatum)
- indinavir (Crixivan®)
- eraviren (Reyataz®)
- nevirapine (Viramune®)
- rifabutin (Mycobutin®)
- rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®)

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- lopinavir/ritonavir (Kaletra®)
- nevirapine (Viramune®)
- indinavir (Crixivan®)
- eraviren (Reyataz®)
- nevirapine (Viramune®)
- rifabutin (Mycobutin®)
- rifampin (Rifater®, Rifamate®, Rimactane®, Rifadin®)

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.