This medicine is used to treat and prevent blood clots in the blood vessels.

People with a heart rhythm problem called atrial fibrillation are at increased risk of a clot forming in the heart. A clot in the heart can dislodge and cause a stroke. Rivaroxaban is used in patients with atrial fibrillation to prevent formation of a clot in the heart and lower the risk of stroke.

Rivaroxaban is also used to treat people who have clots in blood vessels, usually in the legs, arms, or lungs. While it does not dissolve a clot that already exists, this medicine can stop the clot from getting worse and prevent new clots from forming (your body naturally dissolves clots). Rivaroxaban is also used to prevent clots after hip or knee surgery.

This medicine is also called an anticoagulant medicine or blood thinner.

Ask your doctor, pharmacist or nurse to explain anything you do not understand about this medicine.

**Brand names**

- Xarelto
- Xarelto Starter Pack
- There may be other brand names for this medicine

**When this medicine should not be used**

You should not receive this medicine if you have:

- Had an allergic reaction to rivaroxaban.
- Active bleeding.

**How to use this medicine**

Your doctor will prescribe your exact dose and tell you how often it should be given.

- Take this medicine as directed, and take it at the same time each day.
- **10-milligram (mg) tablet**: Take with or without food.
- **15-mg or 20-mg tablet**: Take with food.
- If you cannot swallow the tablets, you may crush the tablet and mix it with applesauce. Eat some food after you swallow the mixture.
- **Tube feeding**: You may crush the tablet and mix the medicine in 50 milliliters (mL) of water before giving it through the tube. This must be followed by a feeding.
- This medicine should come with a Medication Guide. Ask your pharmacist for a copy if you do not have one.
- Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.
**Missed dose**

Ask your doctor or pharmacist if you are not sure what to do if you miss a dose.

- **One dose daily:** If you miss a dose or forget to use your medicine, use it as soon as you can on the same day. Do not use extra medicine to make up for a missed dose.

- **Twice-daily dose to treat a blood clot (15-mg tablet):** If you miss a dose or forget to use your medicine, use it as soon as you can on the same day. You may take 2 doses at the same time to make up for the missed dose. **This is only for people who take a total of 30 mg each day.**

**Drugs and foods to avoid**

**Ask your doctor or pharmacist before using any other medicine,** including over the counter medicines, vitamins and herbal products.

Some foods and medicine can affect how this medicine works. Tell your doctor if you are using any of the following:

- Ketoconazole (Nizoral)
- Itraconazole (Sporanox)
- Medicines for HIV/AIDS such as lopinavir (Kaletra), ritonavir (Norvir), or indinavir (Crixivan)
- Conivaptan (Vaprisol)
- Carbamazepine (Tegretol)
- Phenytoin (Dilantin)
- Rifampin (Rifadin or Rimactane)
- St. John’s wort

**Unless instructed by your doctor, do not take rivaroxaban with another blood thinner,** such as:

- Warfarin (Coumadin or Jantoven)
- Dabigatran (Pradaxa)
- Heparin

You may be at increased risk for bleeding if you take rivaroxaban with:

- Clopidogrel (Plavix)
- Enoxaparin
- Prescription and over-the-counter pain and arthritis medicines:
  - Aspirin (Your doctor may approve of a daily dose of aspirin with rivaroxaban)
  - NSAID medicines such as: celecoxib (Celebrex), diclofenac (Voltaren), ibuprofen (Motrin, Advil and others), naproxen (Naprosyn, Aleve and others)
Warning while using this medicine

- **Serious, life-threatening bleeding can occur with rivaroxaban use. There is no antidote to reverse the effects of this drug.**
- Tell your doctor if you are pregnant or breastfeeding.
- Tell your doctor if you have liver disease, kidney disease, a bleeding problem (such as hemophilia), or an artificial heart valve.
- This medicine may cause nerve damage if you have a medical procedure done on your back, such as a spinal procedure or anesthesia. This is more likely to happen if you have a history of back injury, back surgery, problems with your spine, or procedures or punctures to your back. Tell your doctor if you are also taking another blood thinner, because this also increases the risk.
- You may bleed and bruise more easily while you are using this medicine. Be careful to avoid injuries. Everyday behaviors, such as blowing your nose, clipping fingernails, shaving, or doing sports, can increase your risk for injury. Brush and floss your teeth gently. Talk with your doctor about how to protect yourself while taking this medicine.
- Tell any doctor or dentist who treats you that you are using this medicine. You may need to stop using this medicine for several days before having surgery or medical tests.
- Your doctor will need to check your blood at regular visits while you are using this medicine. Be sure to keep all appointments.
- Carry a card in your wallet or purse that shows you take rivaroxaban. Consider getting a medical alert bracelet or necklace.
- **Do not stop using this medicine suddenly without asking your doctor.** You might have a higher risk of stroke for a short time after you stop this medicine.
- Keep all medicine out of reach of children. Never share your medicine with anyone.

Possible side effects

Tell your doctor right away or seek emergency help if you are not able to reach your doctor if you have:

- Allergic reaction: itching or hives, swelling of the face or hands, swelling or tingling in your mouth or throat, trouble breathing or chest tightness
- Blistering, peeling or red skin rash
- increased menstrual bleeding or vaginal bleeding
- Bloody, pink or brown colored urine
- Severe stomach pain, vomiting blood or material that looks like coffee grounds
- Bloody or black tarry stools
- Unusual bleeding, bruising, including frequent nose bleeds or bleeding gums
If you fall or have an injury to your head, seek medical care, even if you feel okay.

If you have other side effects that you think are caused by this medicine, tell your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-332-1088.

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