**MEDICATION GUIDE**
**Rivaroxaban (RIV-a-ROX-a-ban)**
**Tablets, USP**

**What is the most important information I should know about rivaroxaban tablets?**
**Rivaroxaban tablets may cause serious side effects, including:**

- **Increased risk of blood clots if you stop taking rivaroxaban tablets.** People with atrial fibrillation (a type of irregular heart beat) that is not caused by a heart valve problem (non-valvular) 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. Rivaroxaban tablets lower your chance of having a stroke by helping to prevent clots from forming. If you stop taking rivaroxaban tablets, you may have increased risk of forming a clot in your blood.

  **Do not stop taking rivaroxaban tablets without talking to the doctor who prescribes it for you. Stopping rivaroxaban tablets increases your risk of having a stroke.** If you have to stop taking rivaroxaban tablets, your doctor may prescribe another blood thinner medicine to prevent a blood clot from forming.

- **Increased risk of bleeding.** Rivaroxaban tablets can cause bleeding which can be serious and may lead to death. This is because rivaroxaban is a blood thinner medicine (anticoagulant) that lowers blood clotting. During treatment with rivaroxaban tablets 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 rivaroxaban tablets and have certain other medical problems.

  **You may have a higher risk of bleeding if you take rivaroxaban tablets and take other medicines that increase your risk of bleeding, including:**
  - aspirin or aspirin containing products
  - long-term (chronic) use of 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 or your child 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
- left upper belly (abdominal) pain, pain below the left rib cage or at the tip of your left shoulder or diffuse abdominal discomfort (these may be symptoms of rupture of the spleen)

- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like rivaroxaban tablets, 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 rivaroxaban tablets 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)

Rivaroxaban tablets are not for use in people with artificial heart valves.
Rivaroxaban tablets are not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing.

**What are rivaroxaban tablets?**
Rivaroxaban tablets are prescription medicine used to:
- reduce the risk of stroke and blood clots in adults who have a medical condition called atrial fibrillation that is not caused by a heart valve problem. 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 DVT) or lungs (pulmonary embolism or PE)
- reduce the risk of blood clots from happening again in adults who continue to be at risk for DVT or PE after receiving treatment for blood clots for at least 6 months.
- help prevent a blood clot in the legs and lungs of adults who have just had hip or knee replacement surgery
- help prevent blood clots in certain adults hospitalized for an acute illness and after discharge who are at risk of getting blood clots because of the loss of or decreased ability to move around (mobility) and other risks for getting blood clots and who do not have a high risk of bleeding.

Rivaroxaban tablets are used with low dose aspirin to:
- reduce the risk of serious heart problems, heart attack and stroke in adults with coronary artery disease (a condition where the blood supply to the heart is reduced or blocked)
- reduce the risk of a sudden decrease in blood flow to the legs, major amputation,

serious heart problems or stroke in adults with peripheral artery disease (a condition where the blood flow to the legs is reduced) and includes adults who have recently had a procedure to improve blood flow to the legs.

Rivaroxaban tablets are used in children to:

- treat blood clots or reduce the risk of blood clots from happening again in children from birth to less than 18 years, after receiving at least 5 days of treatment with injectable or intravenous medicines used to treat blood clots.
- help prevent blood clots in children 2 years and older with congenital heart disease after the Fontan procedure.

Rivaroxaban tablets were not studied and is not recommended in children less than 6 months of age who:

- were less than 37 weeks of growth (gestation) at birth
- had less than 10 days of oral feeding, or
- had a body weight of less than 5.7 pounds (2.6 kg)

**Do not take rivaroxaban tablets if you or your child:**

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

**Before taking rivaroxaban tablets, tell your doctor about all of your medical conditions, including if you or your child:**

- have or ever had bleeding problems
- have liver or kidney problems
- have antiphospholipid syndrome (APS)
- are pregnant or plan to become pregnant. It is not known if rivaroxaban tablets will harm your unborn baby.
  - **Tell your doctor** right away if you become pregnant during treatment with rivaroxaban tablets. Taking rivaroxaban tablets while you are pregnant may increase the risk of bleeding in you or in your unborn baby.
  - Females who are able to become pregnant: Talk with your doctor about pregnancy planning during treatment with rivaroxaban tablets. Talk with your doctor about your risk for severe uterine bleeding if you are treated with blood thinner medicines, including rivaroxaban tablets.
  - If you take rivaroxaban tablets during pregnancy **tell your doctor** right away if you have any signs or symptoms of bleeding or blood loss. See "**What is the most important information I should know about rivaroxaban tablets?**" **for signs and symptoms of bleeding.**
- are breastfeeding or plan to breastfeed. Rivaroxaban can pass into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with rivaroxaban tablets.

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

**Tell your doctor about all the medicines you or your child take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some of your other medicines may affect the way rivaroxaban tablets works causing side effects. Certain medicines may increase your risk of bleeding. See **"What is the most important information I should know about rivaroxaban tablets?**"

**Especially tell your doctor if you take or your child:**

- ketoconazole
- ritonavir
- erythromycin
- carbamazepine
- phenytoin
- rifampin
- St. John's wort

**How should I take rivaroxaban tablets?**

- Take rivaroxaban tablets exactly as prescribed by your doctor.
- **Do not change your dose or stop taking rivaroxaban tablets unless your doctor tells you to.** Your doctor may change your dose if needed.
- Your doctor will decide how long you should take rivaroxaban tablets.
- Rivaroxaban tablets may need to be stopped for one or more days before any surgery or medical or dental procedure. Your doctor will tell you when to stop taking rivaroxaban tablets and when to start taking rivaroxaban tablets again after your surgery or procedure.
- If you need to stop taking rivaroxaban tablets for any reason, talk to the doctor who prescribed rivaroxaban tablets to you to find out when you should stop taking it. Do not stop taking rivaroxaban tablets without first talking to the doctor who prescribes it to you.
- If you have difficulty swallowing rivaroxaban tablets whole, talk to your doctor about other ways to take rivaroxaban tablets.
- Do not run out of rivaroxaban tablets. Refill your prescription of rivaroxaban tablets before you run out. When leaving the hospital following a hip or knee replacement, be sure that you will have rivaroxaban tablets available to avoid missing any doses.
- If you take too much rivaroxaban tablets, go to the nearest hospital emergency room or call your doctor right away.

**If you take rivaroxaban tablets for:**

- **Atrial fibrillation that is not caused by a heart valve problem:**
  - Take rivaroxaban tablets **1 time a day with your evening meal**.
  - If you miss a dose of rivaroxaban tablets, 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 rivaroxaban tablets **1 or 2 times a day** as prescribed by your doctor.
  - For the **10 mg dose**, take rivaroxaban tablets **with or without food.**
  - For the **15 mg and 20 mg doses**, take rivaroxaban tablets **with food at the same time each day.**
  - If you miss a dose:
    - **If you take the 15 mg dose of rivaroxaban tablets 2 times a day (a total of 30 mg of rivaroxaban tablet in 1 day):** Take rivaroxaban tablets 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.
    - **If you take rivaroxaban tablets 1 time a day:** Take rivaroxaban tablets as soon as you remember on the same day. Take your next dose at your regularly scheduled time.

- **Hip or knee replacement surgery:**
  - Take rivaroxaban tablets 1 time a day with or without food.
  - If you miss a dose of rivaroxaban tablets, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- **Blood clots in people hospitalized for an acute illness:**
  - Take rivaroxaban tablets 1 time a day, with or without food, while you are in the hospital and after you are discharged as prescribed by your doctor.
  - If you miss a dose of rivaroxaban tablets, take it as soon as you remember on the same day. Take your next dose at your regularly scheduled time.
- **Reducing the risk of serious heart problems, heart attack and stroke in coronary artery disease:**
  - Take rivaroxaban tablets 2.5 mg 2 times a day with or without food.
  - If you miss a dose of rivaroxaban tablets, take your next dose at your regularly scheduled time.
  - Take aspirin 75 to 100 mg once daily as instructed by your doctor.
- **Reducing the risk of a sudden decrease in blood flow to the legs, major amputation, serious heart problems or stroke in people with peripheral artery disease including those who have recently had a procedure to improve blood flow to the legs:**
  - Take rivaroxaban tablets 2.5 mg 2 times a day with or without food.
  - If you miss a dose of rivaroxaban tablets, take your next dose at your regularly scheduled time.
  - Take aspirin 75 mg to 100 mg 1 time a day as instructed by your doctor.

**For children who take rivaroxaban tablets**

- The dose of rivaroxaban tablets depends on your child's body weight and will be calculated by your child's doctor. Your child's doctor will tell you if rivaroxaban tablets can be given to your child with or without food.
- The adult caregiver should give the dose.
- If your child is taking the tablet, the tablet should be taken whole and should not be split in an attempt to provide a lower dose of rivaroxaban tablets.
- Do not switch between the rivaroxaban oral suspension or tablets without first talking to your doctor.
- If your child vomits or spits up:
  - if vomiting or spitting up persists, contact your child's doctor right away.
- If your child misses a dose:
  - If your child is taking rivaroxaban tablets 1 time a day, give the dose as soon as you remember on the same day. If this is not possible, skip this dose and give the next dose at the regularly scheduled time.
  - If your child is taking rivaroxaban tablets 2 times a day, give the missed morning dose as soon as you remember. You may give the missed morning dose together with the evening dose. However, a missed evening dose can only be taken in the same evening.
  - If your child is taking rivaroxaban tablets 3 times a day, skip the missed dose and give the next dose at the regularly scheduled time.

**What are the possible side effects of rivaroxaban tablets?**

**Rivaroxaban tablets may cause serious side effects:**

- See "**What is the most important information I should know about rivaroxaban tablets?**"

**The most common side effect of rivaroxaban tablets in adults was bleeding.**

**The most common side effects of rivaroxaban tablets in children include**:

- bleeding
- cough
- vomiting
- inflamed stomach and gut

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effect to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit www.lupin.com.

**How should I store rivaroxaban tablets?**

- Store rivaroxaban tablets at room temperature between 59 °F to 86 °F (15 °C to 30 °C).

**Keep rivaroxaban tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of rivaroxaban tablets.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rivaroxaban tablets for a condition for which it was not prescribed. Do not give rivaroxaban tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about rivaroxaban tablets that is written for health professionals.

**What are the ingredients in rivaroxaban tablets?**

Active ingredient: rivaroxaban

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

The proprietary film coating mixture for rivaroxaban tablets, 2.5 mg is Opadry® Yellow containing hypromellose, iron oxide yellow, macrogol / PEG and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 10 mg is Opadry® Pink and contains: iron oxide red, hypromellose, macrogol / PEG, and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 15 mg is Opadry® Brown and contains: iron oxide red, hypromellose, macrogol / PEG, and titanium dioxide.

The proprietary film coating mixture for rivaroxaban tablets 20 mg is Opadry® White and contains: hypromellose, macrogol / PEG and titanium dioxide.

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