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## MEDICATION GUIDE

### Rivaroxaban (RIV-a-ROX-a-ban) for Oral Suspension

**What is the most important information I should know about rivaroxaban for oral suspension?**

**Rivaroxaban for oral suspension may cause serious side effects, including:**

- **Increased risk of blood clots if you stop taking rivaroxaban for oral suspension.** 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 for oral suspension lowers your chance of having a stroke by helping to prevent clots from forming. If you stop taking rivaroxaban for oral suspension, you may have increased risk of forming a clot in your blood.

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

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

**You may have a higher risk of bleeding if you take rivaroxaban for oral suspension 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<sup>®</sup>, Jantoven<sup>®</sup>)
- any medicine that contains heparin
- clopidogrel (Plavix<sup>®</sup>)
- 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 for oral suspension, 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 for oral suspension 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
- muscle weakness (especially in your legs and feet)
- tingling
- loss of control of the bowels or bladder (incontinence)
- numbness

Rivaroxaban for oral suspension is not for use in people with artificial heart valves.

Rivaroxaban for oral suspension is not for use in people with antiphospholipid syndrome (APS), especially with positive triple antibody testing.

### **What is rivaroxaban for oral suspension?**

Rivaroxaban for oral suspension is 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 for oral suspension was 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 for oral suspension if you or your child:**

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

**Before taking rivaroxaban for oral suspension, 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 for oral suspension will harm your unborn baby.
  - **Tell your doctor** right away if you become pregnant during treatment with rivaroxaban for oral suspension. Taking rivaroxaban for oral suspension 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 for oral suspension. Talk with your doctor about your risk for severe uterine bleeding if you are treated with blood thinner medicines, including rivaroxaban for oral suspension.
  - If you take rivaroxaban for oral suspension 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 for oral suspension?” 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 for oral suspension.

**Tell all of your doctors and dentists** that you or your child are taking rivaroxaban for oral suspension. They should talk to the doctor who prescribed rivaroxaban for oral suspension 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 for oral suspension works, causing side effects. Certain medicines may increase your risk of bleeding. See **“What is the most important information I should know about rivaroxaban for oral suspension?”**

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

- |                   |                 |
|-------------------|-----------------|
| • ketoconazole    | • ritonavir     |
| • erythromycin    | • carbamazepine |
| • phenytoin       | • rifampin      |
| • St. John’s wort |                 |

**How should I take rivaroxaban for oral suspension?**

- Take rivaroxaban for oral suspension exactly as prescribed by your doctor.
- **Do not change your dose or stop taking rivaroxaban for oral suspension unless your doctor tells you to.** Your doctor may change your dose if needed.
- Your doctor will decide how long you should take rivaroxaban for oral suspension.
- Rivaroxaban for oral suspension 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 for oral suspension and when to start taking rivaroxaban for oral suspension again after your surgery or procedure.
- If you need to stop taking rivaroxaban for oral suspension for any reason, talk to the doctor who prescribed rivaroxaban for oral suspension to you to find out when you should stop taking it. Do not stop taking rivaroxaban for oral suspension without first talking to the

doctor who prescribes it to you.

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

**For children who take rivaroxaban for oral suspension:**

- The dose of rivaroxaban for oral suspension 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 for oral suspension can be given to your child with or without food.
- The adult caregiver should give the dose.
- If your child is taking the oral suspension, use the syringes provided in the original carton. The suspension will be prepared by the pharmacy. See the **Instructions for Use** included in the carton on how to properly give a dose of rivaroxaban for oral suspension to your child.
- Do not switch between the rivaroxaban for oral suspension or tablet without first talking to your doctor.
- If your child vomits or spits up:
  - right after or within 30 minutes of taking the oral suspension, give a new full dose.
  - more than 30 minutes after taking the oral suspension, do not give the dose again. Give the next dose at the regularly scheduled time.
  - 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 for oral suspension 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 for oral suspension 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 for oral suspension 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 for oral suspension?**

**Rivaroxaban for oral suspension may cause serious side effects:**

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

**The most common side effects of rivaroxaban for oral suspension 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 1800-FDA-1088. You may also report side effect to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit [www.lupin.com](http://www.lupin.com).

**How should I store rivaroxaban for oral suspension?**

- Store rivaroxaban for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Store syringes and bottle upright in the original carton for rivaroxaban for oral suspension.
- **Do not** freeze rivaroxaban for oral suspension.

**Keep rivaroxaban for oral suspension and all medicines out of the reach of children.**

Discard rivaroxaban for oral suspension after “Discard after” date written on the bottle.

**General information about the safe and effective use of rivaroxaban for oral suspension.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use rivaroxaban for oral suspension for a condition for which it was not prescribed. Do not give rivaroxaban for oral suspension 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 for oral suspension that is written for health professionals.

**What are the ingredients in rivaroxaban for oral suspension?**

**Active ingredient:** rivaroxaban

**Inactive ingredients:**

anhydrous citric acid, carboxymethylcellulose sodium, hydroxypropyl methyl cellulose, mannitol, microcrystalline cellulose, sodium benzoate, sucralose, tutti frutti flavor and xanthan gum.

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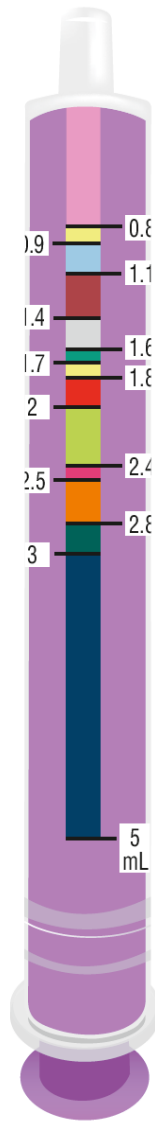
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India

Revised: June 2025

ID#: xxxxxx

**Instructions for Use**  
**Rivaroxaban (RIV-a-ROX-a-ban) for Oral Suspension**



This Instructions for Use contains information on how to give a dose of rivaroxaban for oral suspension.

Read this Instructions for Use before giving rivaroxaban for oral suspension and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your child's medical condition or treatment.

**Important Information:**

- Rivaroxaban for oral suspension is for oral use only.
- Give rivaroxaban for oral suspension to your child exactly as prescribed by your doctor. The adult caregiver should give the dose. If you have questions, contact your doctor or pharmacist for more information on giving a dose.
- **Only use the oral dosing syringe provided with rivaroxaban for oral suspension.**  
Contact your doctor or pharmacist if the oral dosing syringe is missing, lost or damaged.

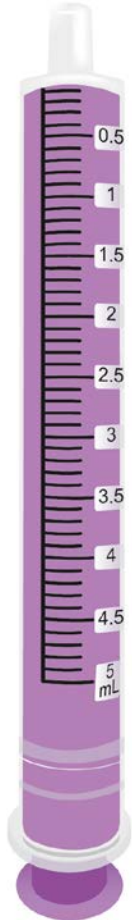
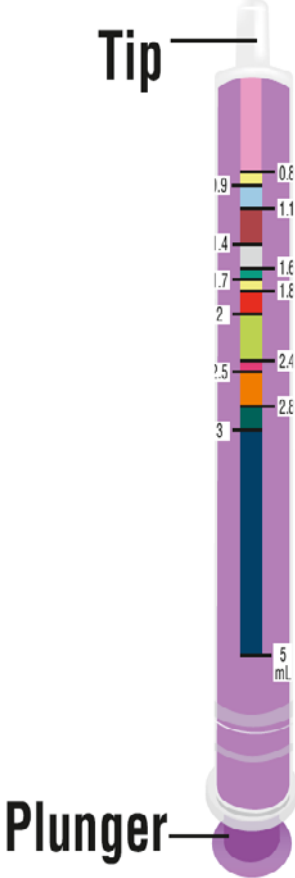
**Storage Information:**

Store rivaroxaban for oral suspension at room temperature between **68°F to 77°F** (20°C to 25°C). **Do not** freeze.

Store the bottle upright with the oral dosing syringes in the original carton.

**Keep rivaroxaban for oral suspension and all medicines out of reach of children.**

**Rivaroxaban for Oral Suspension Oral Dosing Syringe:**

Side 1: Dosing in milliliters (mL)	Side 2: Dosing with color band * (mL)
	 <p><b>Tip</b> —</p> <p><b>Plunger</b> —</p> <p><b>*This color band is an aid to withdraw the prescribed dose.</b></p>



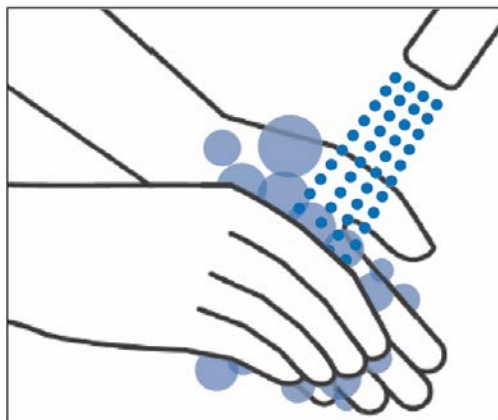
## Rivaroxaban for Oral Suspension Bottle



### Step 1: Get Ready



**Check “Discard after” date on the rivaroxaban for oral suspension bottle.**  
If “Discard after” date has passed, **do not** use and call your doctor or pharmacist.



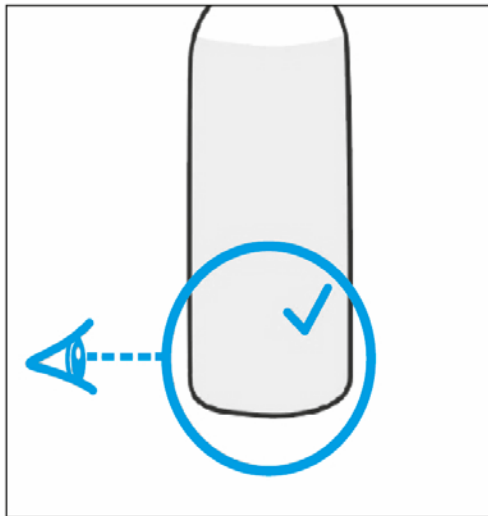
Wash hands.  
Wash your hands well with soap and warm water.

## Step 2: Prepare Rivaroxaban for Oral Suspension



**Shake bottle slowly for 10 seconds before each use.**

**Do not** shake the bottle too fast to avoid foaming.  
Foaming may lead to giving the wrong dose.



**Check rivaroxaban for oral suspension.**

If there are lumps or granules at the bottom of the bottle, shake the bottle **slowly** again for **10 seconds**.

## Step 3: Check the prescribed dose

**Find your dose line.**

You can use either side of the syringe to set your dose.

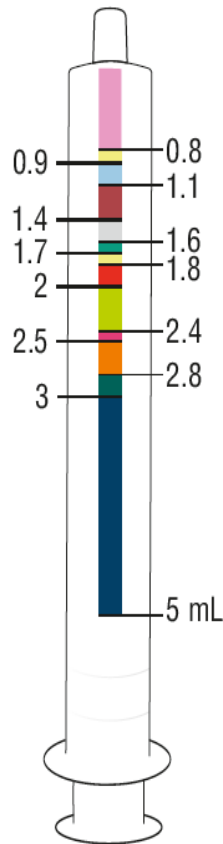
**If using mL side of syringe:**

Top of the plunger should line up with the prescribed mL.

**If using color side of syringe:**

Top of the plunger should line up with the prescribed mL dose line at the **bottom of the color band**.

**Only use the oral dosing syringe provided with rivaroxaban for oral suspension.**

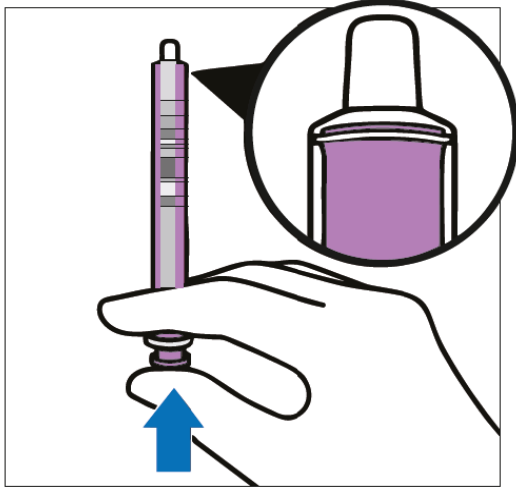


**If your dose is more than 5 mL.**

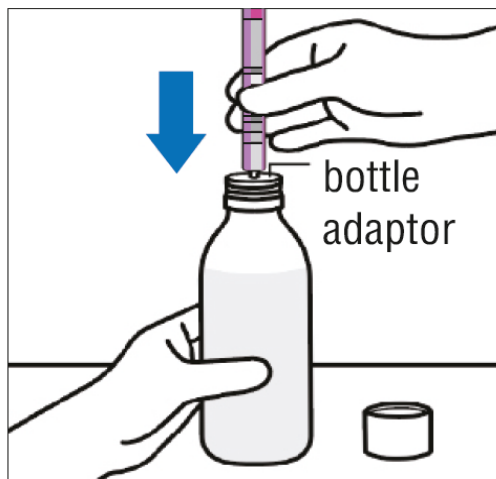
You will need to use the same syringe more than one time. Repeat Steps 4 and 5 to complete your dose. Ask your pharmacist if you are not sure.

Dose	Measure
7.5 mL	5 mL + 2.5 mL
10 mL	5 mL + 5 mL
15 mL	5 mL + 5 mL + 5 mL
20 mL	5 mL + 5 mL + 5 mL + 5 mL

#### Step 4: Set prescribed dose



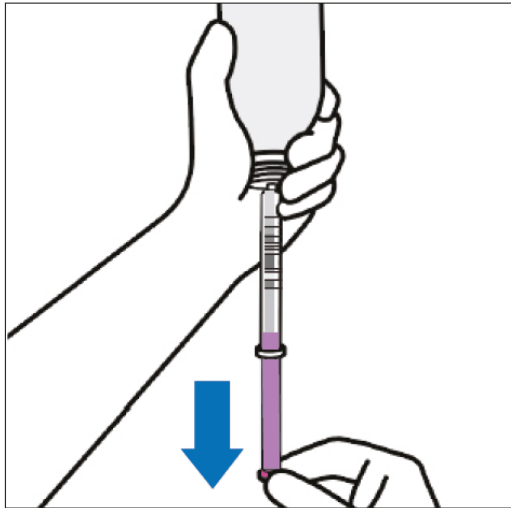
**Push plunger all the way in to remove air.**



**Insert oral dosing syringe into bottle adaptor.**

Twist off the cap from the bottle.

**Do not** remove the bottle adaptor from the bottle. Insert the syringe tip into the bottle adaptor.



**Fill oral dosing syringe.**

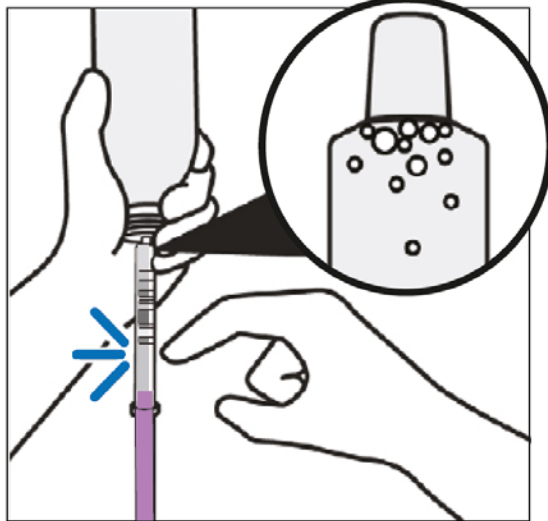
Turn the bottle upside down, as shown.

Pull the plunger to fill the oral dosing syringe **slightly past your prescribed dose line to help** remove any air bubbles.



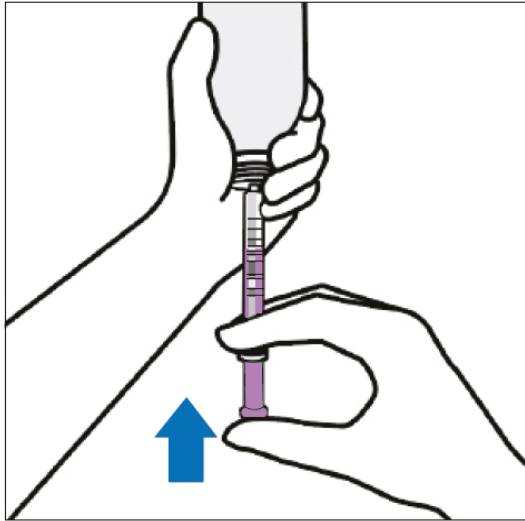
**CAUTION:**

**Make sure you have enough medicine for a full dose. Do not take a partial dose.**



**Tap syringe to move air bubbles to the top.**

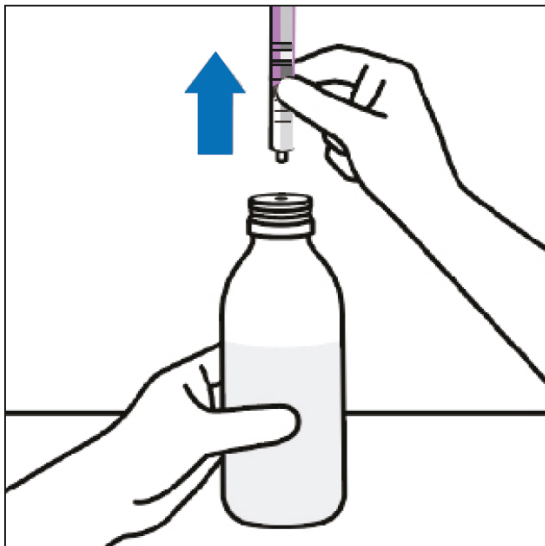
Doing this helps set the correct dose.



**Adjust to your prescribed dose.**

**If using mL side of syringe:** Push plunger to align with the prescribed dose line.

**If using color side of syringe:** Push plunger to align with the prescribed mL dose line at the bottom of the color band.

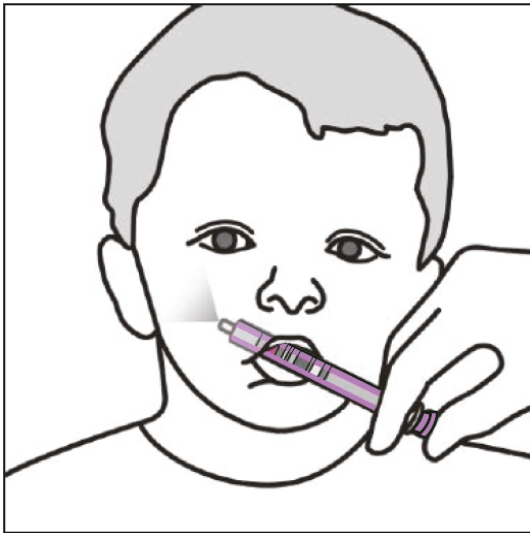


**Remove oral dosing syringe.**

Place the bottle on a flat surface.

Remove the oral dosing syringe from the bottle.

### Step 5: Give the dose



#### Give the dose.

Place the oral dosing syringe gently into the child's mouth with **the tip of the syringe pointing toward the cheek and slowly press the plunger.**

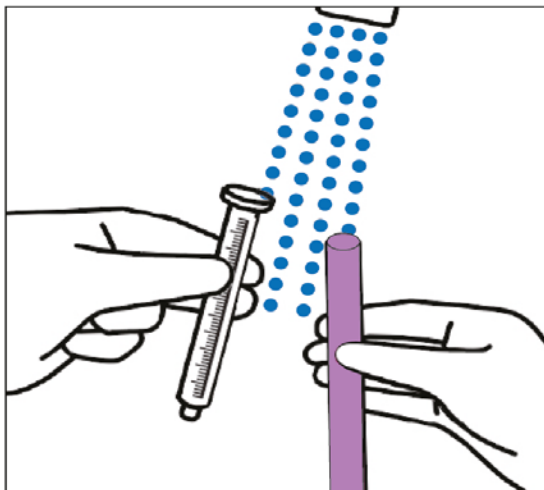
This allows the child to swallow naturally.

Make sure the child swallows the full dose.

If your child vomits or spits out the medicine repeatedly, contact your child's doctor right away.

If your dose is **more than 5 mL**, you will need to use the same syringe more than one time.  
Repeat Steps 4 and 5 to complete your dose.

### Step 6: Rinse and store



**Close rivaroxaban for oral suspension bottle and rinse oral dosing syringe.**

Rinse the oral dosing syringe with tap water and let it air dry.

**Do not place the oral dosing syringe in the dishwasher.**

**Disposing rivaroxaban for oral suspension bottle and syringe**

- Throw the rivaroxaban for oral suspension bottle away in your household trash.
- Throw away any used oral dosing syringe with the opening of a new rivaroxaban for oral suspension bottle.
- **Do not pour rivaroxaban for oral suspension down the drain** (for example: sink, toilet, shower or tub).
- **Do not** recycle the bottle.

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Revised: June 2025

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