

# Instructions for Use

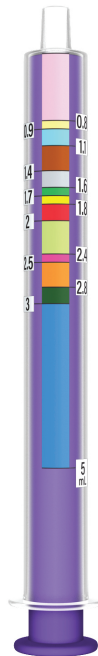
## XARELTO®

### (zah-REL-toe)

### (rivaroxaban)

#### for oral suspension

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



Read this Instructions for Use before giving XARELTO 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:

- XARELTO suspension is for oral use only.
- Give XARELTO 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 XARELTO oral suspension.** Contact your doctor or pharmacist if the oral dosing syringe is missing, lost or damaged.

#### Storage information

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

**Do not** freeze.

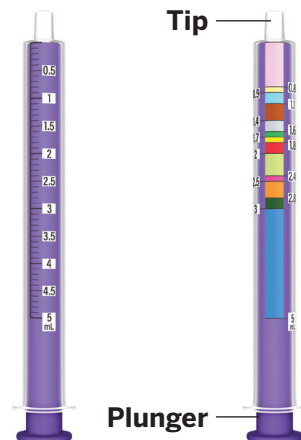
Store the bottle upright with the oral dosing syringes in the original carton.

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

#### XARELTO Oral Dosing Syringe:

**Side 1:**  
Dosing in  
milliliters  
(mL)

**Side 2:**  
Dosing with  
color band\*  
(mL)

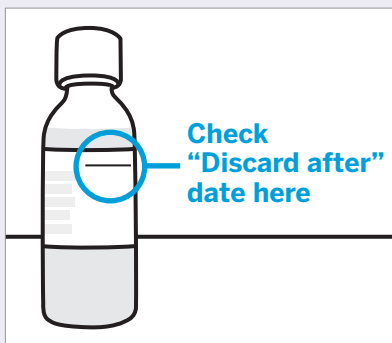


\* The color band is an aid to withdraw the prescribed dose.

#### XARELTO Bottle



### Step 1 Get ready



#### Check "Discard after" date on the XARELTO bottle.

If "Discard after" date has passed, **do not** use and call your doctor or pharmacist.



#### Wash hands.

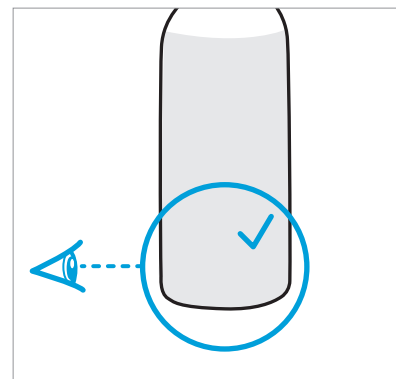
Wash your hands well with soap and warm water.

### Step 2 Prepare XARELTO



#### 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 XARELTO 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:

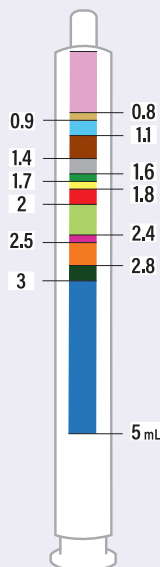
Top of the plunger should line up with the prescribed mL dose line at the **bottom of the color band**.

**Only use the oral dosing syringe provided with XARELTO oral suspension.**

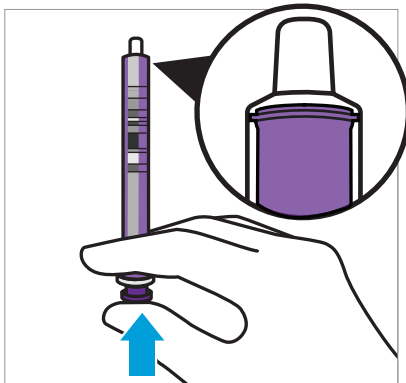
#### If your dose is more than 5 mL.

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.

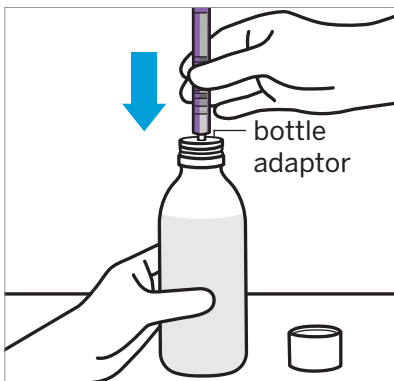
Dose	Measure
7.5 mL	5 mL + 2.5 mL
10 mL	5 mL + 5 mL
15 mL	5 mL + 5 mL + 5 mL
20 mL	5 mL + 5 mL + 5 mL + 5 mL



## Step 4 Set prescribed dose



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

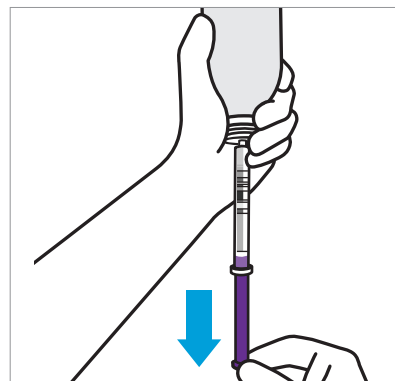


**Insert oral dosing syringe into bottle adaptor.**

Twist off the cap from the bottle.

**Do not** remove the bottle adaptor from the bottle.

Insert the syringe tip into the bottle adaptor.



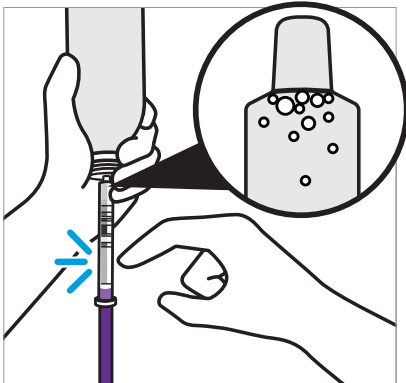
**Fill oral dosing syringe.**

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.

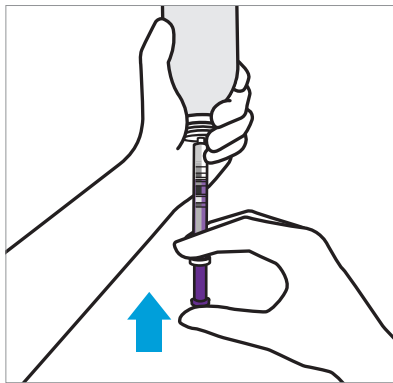
**⚠ CAUTION:**  
**Make sure you have enough medicine for a full dose.**  
**Do not take a partial dose.**

**Step 4 Set prescribed dose (continued)**



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

Doing this helps set the correct dose.



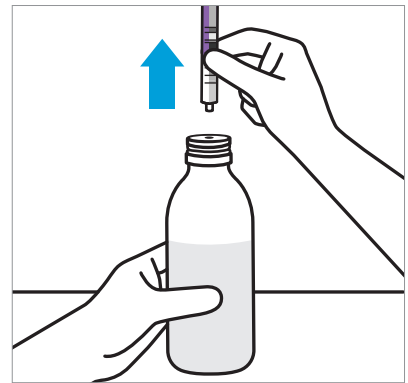
**Adjust to your prescribed dose.**

**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.

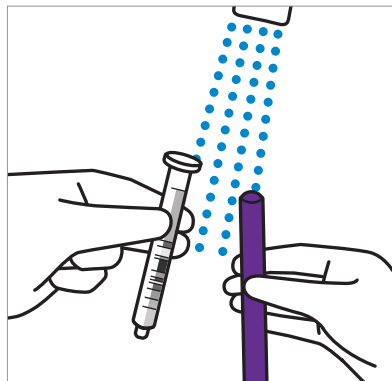
Place the oral dosing syringe gently into the child's mouth with **the tip of the syringe pointing toward the cheek and slowly press the plunger.** This allows the child to swallow naturally.

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 XARELTO 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 XARELTO bottle and syringe

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

Active ingredient made in Germany.

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

Licensed from:  
Bayer HealthCare AG  
51368 Leverkusen, Germany  
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Companies

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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