

Instructions for Use (IFU)

Instructions for Use

Xarelto 1 mg/mL

Bottle with 2.625 g granules for preparation of oral suspension

Active pharmaceutical ingredient: Rivaroxaban

Preparation and administration of the oral suspension (granules-water-mixture)

Glossary and symbols

- Granules: powder (provided in the bottle) which contains active pharmaceutical ingredient
- Water syringe: 50 mL syringe used to measure and add 50 mL of water to the bottle containing Xarelto granules.
- Suspension: granules-water-mixture (for oral application)
- Blue syringe: syringe with blue plunger to extract and orally administer Xarelto.



Caution: Consult Instructions for Use for relevant information related to warnings and precautions.



Consult Instructions for Use (IFU).



Keep away from sunlight



Protect from moisture



Manufacturer



Manufacturing date



Expiry date



Reference number



Batch number



For oral use only



Blue syringe - Single patient, multiple use



Water syringe – single use only and do not re-use



Do not use if package is damaged



Medical Device



CE marking of conformity

Before you start

- Read all sections of the Instructions for Use carefully before using Xarelto for the first time and before administering each dose.
- Watch the educational video which you can access via the QR code displayed on the Patient Alert Card that is provided with this medicine.
- Be sure you understand the instructions before starting. If not, call your doctor.
- Further information regarding Xarelto can be found in the Package Leaflet

Packaging contents

Every Xarelto box contains the following components:



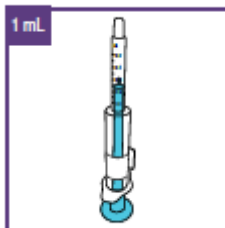
1 bottle with child resistant screw cap containing Xarelto granules.



1 packaged water syringe (for single use only)



1 packaged bottle adapter



2 packaged 1 mL blue syringes



1 Instructions for Use (IFU) (this document)



1 Package Leaflet
Provides important information about Xarelto.



1 Patient Alert Card

Important information in case of emergency.

To be kept with the patient at all times and presented to every physician or dentist prior to treatment



Cautionary Information:

Do not unpack the single components until the instructions tell you to do so.

Do not use Xarelto if any of the parts have been opened or are damaged.

Do not use Xarelto after the expiry date which is stated on the box.

Warnings and precautions

- **Only** use non-carbonated drinking water to prepare the suspension to avoid bubbles. That means you can use either
 - fresh tap water or
 - non-carbonated (still) mineral water
- It is very important that the precise amount of water is added to the granules in the bottle to ensure the correct concentration of Xarelto.
 - Use the water syringe for measurement of 50 mL water, see below for more information.
 - Measure the amount water to be provided to the bottle very carefully.
- After preparation the suspension can be used for 14 days if stored at room temperature. Ensure to write the expiry date of the suspension (date of preparation plus 14 days) on the dedicated field on the bottle label.
- **Do not** store the suspension above 30 °C. **Do not** freeze.
If the suspension has been stored in the refrigerator, allow the suspension to adjust to room temperature before extracting the relevant dose.
- Shake the suspension for initial preparation **for at least 60 seconds**.
- Shake the suspension in the bottle **for at least 10 seconds** before each administration.
- It is very important that the prescribed dose volume of Xarelto is being administered.
 - Make sure that you know the prescribed dose and frequency of administration. Ask your doctor or pharmacist if you do not know the prescribed dose and frequency.
 - Carefully adjust the blue syringe according the prescribed volume.
 - Administer the prescribed dose by using the blue syringe. Follow the doctor's instructions on how often per day you should administer the prescribed dose.
 - Check for air bubbles in the blue syringe before administration of the oral suspension.
- If your child repeatedly does not take all the required dose or spits some of it out, call your child's doctor to find out what to do.
- Between dosing, store the oral suspension out of sight and reach of children.
- Keep the Instructions for Use so that you can refer to them later during the use of Xarelto.

Using Xarelto

- Xarelto suspension is for oral use only.
- Volume and frequency of administration of Xarelto depend on your child's weight, so it will change over time if your child will receive Xarelto for a longer time.
 - Your child's doctor will tell you the right dose volume .
 - **Do not change the dose yourself.**
 - **Always** use the volume prescribed by your child's doctor and have the correct dosing of

administration written on the designated field on the outside of the box.

If it is not written on the field, ask your child's doctor or pharmacist to provide the relevant information.

- Follow the detailed Instructions for Use given in the chapters below.
Take care to comply with the instructions concerning administration (see package leaflet).

1. Preparing the oral suspension

Step 1.1: Preparation – Get ready

The preparation of the suspension is done once with every new package.

Before preparing the suspension:



- a. Thoroughly wash your hands with soap and dry them afterwards



- b. Check the expiry date on the label provided on the box.
Do not use the medicine if the medicine has expired.

- c. Obtain the following additional items:

- Container with at least 150 mL of water:
 - Either fresh tap water or non-carbonated (still) mineral water
 - Water should be at room temperature
- Tissue for soaking up any excess water

Step 1.2: Filling the required volume of water

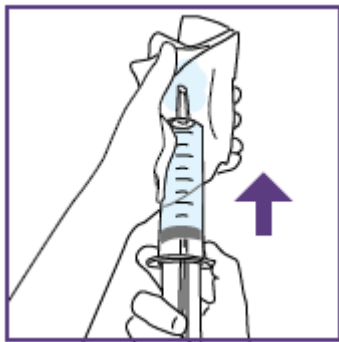
Every time you start a new pack, use only the new materials contained in the new package.

- a. Unpack the water syringe.

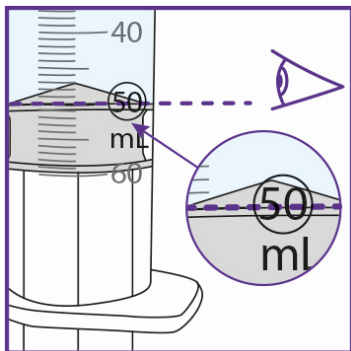


- b. Dip the opening of the water syringe into the container with water.
- c. Extract a volume of more than 50 mL.
To do this, pull the plunger rod towards you, and make sure that the opening of the water syringe stays below the water surface all the time. This will avoid air bubbles in the syringe.
- d. Take the syringe out of the water.

- e. Turn the water syringe in a way that the opening is facing upwards.
→ Any air bubbles will move to the top when holding the syringe upwards.
Tap it with your fingers to further move any air bubble to the top.

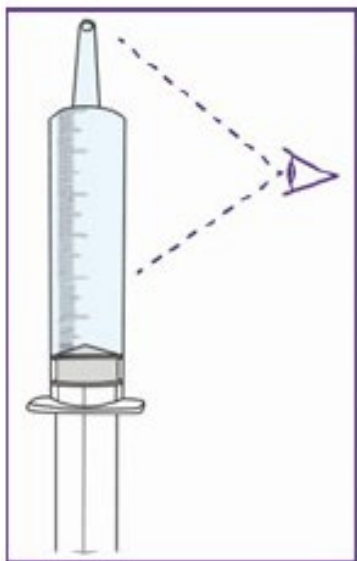


- f. Push the plunger rod until the upper ring of the plunger reaches the 50 mL mark.
→ When pressing the plunger, water can come out of the tip of the water syringe. This waste water can be soaked up with a tissue.



Cautionary Information:

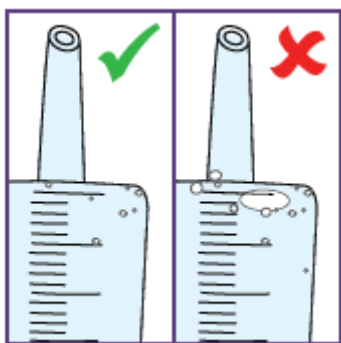
The upper ring of the black plunger **must be precisely in line with the 50 mL** mark to be able to achieve the correct concentration of the suspension.



g. Continue to hold the water syringe with the opening facing upwards and check the water in the syringe carefully:

- for correct volume,
- for air bubbles.

Small air bubbles are uncritical, but big air bubbles are critical. See below for more explanation on what to do.



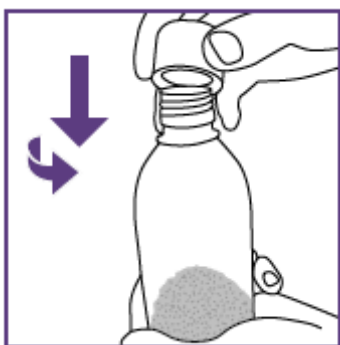
h. **If the syringe is not loaded correctly or contains too much air:**

- Empty the water syringe
- Repeat steps b. to h

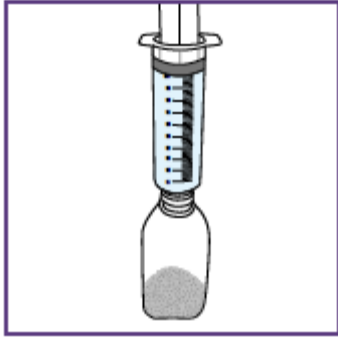
Step 1.3: Adding water to the granules

a. **If the granules in the bottle appear to be clumpy:**

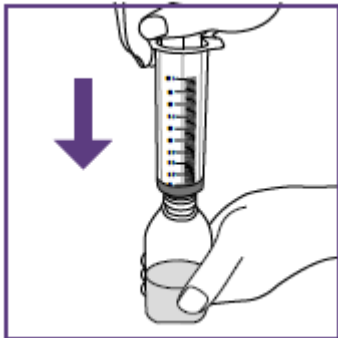
- Gently tap the bottle on your hand.
- **Be careful** since the bottle is made of glass.



b. Unscrew the child resistant cap of the bottle (push down and turn counterclockwise).



c. Place the filled water syringe on the upper edge of the bottle opening



d. Hold the bottle firmly.

e. Press the plunger rod down slowly.

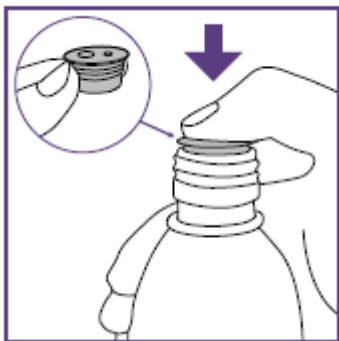
The full volume of water must be transferred to the bottle.

f. Dispose of the water syringe in household waste.

Step 1.4: Fitting the adapter and mixing the oral suspension

The adapter is used to fill the blue syringe with suspension.

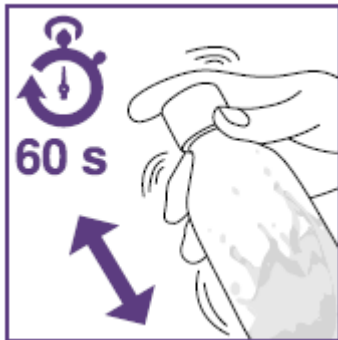
a. Unpack the bottle adapter



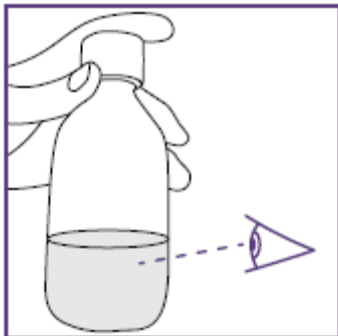
b. Push the adapter completely into the neck of the bottle



c. Close the bottle tightly with the screw cap.



d. Shake the bottle **gently** for **at least 60 seconds**.
 → This is intended to provide a well-mixed suspension.



e. Check whether the suspension is thoroughly mixed:

- no clumps
- no deposit.



Cautionary Information:

To guarantee correct dose, the suspension must **not** contain **any** clumps or deposit.

f. **If there are clumps or sediment** repeat steps d. to f.

→ When no clumps or deposits are left, the suspension is ready for use.

Do not add more water to the bottle.

The suspension has a shelf life of 14 days at room temperature.



g. Write the date of expiry of the just prepared suspension on the label of the bottle.

Date of preparation + 14 days

The shown pictogram is only an example.

2. Setting the prescribed dose with every new blue syringe

To prevent overdosing or underdosing an exact dose of suspension is required.

Before you take the first dose out of the bottle, the enclosed blue syringe must be set up in accordance with the dose prescribed by your child's doctor. This information can be found on the dedicated area of the box. If no information has been entered here check back with the child's doctor or pharmacist.

After setting the dose the same blue syringe can be used for all administrations from the bottle of suspension prepared in step 1.

Once the dose has been fixed on the blue syringe, it cannot be changed.

The blue syringe features a scale (mL).

The scale of the 1 mL blue syringe starts with 0.2 mL.

The graduation marks are in increments of 0.1 mL.

Note:

Do not remove the peelable label until you are prompted in the Instructions for Use.

The blue syringe features a **red** button to adjust the volume.

This button is initially covered by a peelable label.

By pressing the red button the volume of the syringe is set, which can only be done once. **Do not** press the **red** button until the Instructions for Use tell you to do so.

Once the **red** button has been pressed, the volume can no longer be adjusted.

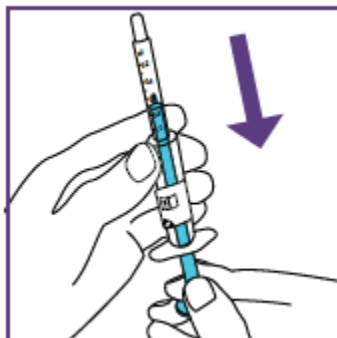


- a. Review the dose provided in the respective field on the outside of the box.

- b. **If the information is not available:**

Ask your pharmacist or doctor to provide it.

- c. Hold the blue syringe with the opening pointing upwards



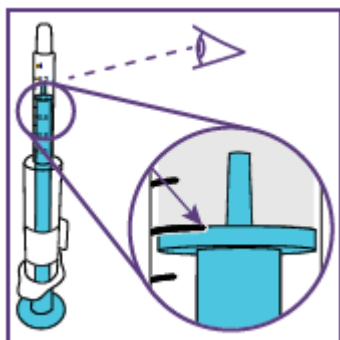
- d. Pull the plunger rod **slowly** until the upper margin reaches the mark of the volume to be administered.

→ When moving the plunger rod, you can hear a “Click” for each adjustable volume step.



Cautionary Information:

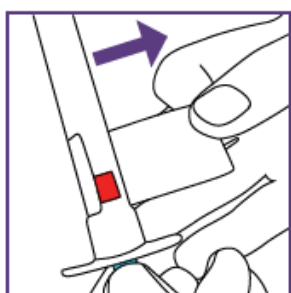
The upper edge of the plunger **must be exactly in line** with the correct mark of the volume to be administered.



The shown pictogram is only an example. Your volume might be different.

Be careful, do not pull the plunger past the volume to be administered.

Be careful, do not press on the label when pulling the plunger.



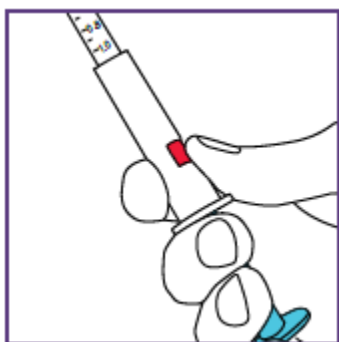
e. Remove the label of the blue syringe **completely**.

→ You can now see the **red** button for setting the volume.

f. Check the position of the plunger again. Ensure the upper edge of the plunger is exactly in line with the correct mark of the volume to be administered.

g. **If the position of the blue plunger does not match the required volume:**

Adjust it accordingly



h. If the position of the blue plunger matches the required volume, push the **red** button to fix the adjustment.

→ The required dose is now set.

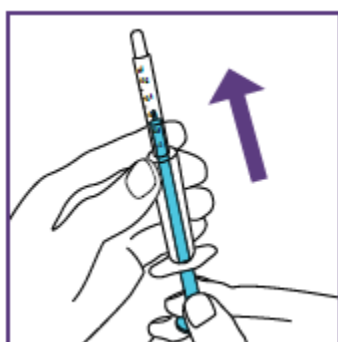
→ Pressing the red button will produce another clicking sound.

The clicking sound will not be audible afterwards.



Cautionary Information:

If you notice that the wrong dose has been selected (the red button has been pushed, when the plunger was in the wrong position) use the appropriate spare blue syringe. Repeat steps a. to h. with a new blue syringe.



i. Push the plunger upwards in the blue syringe as far as it goes.

The blue syringe can now be used.

3. Administering the oral suspension

Follow the steps described below for each required administration.

Step 3.1: Mixing the oral suspension



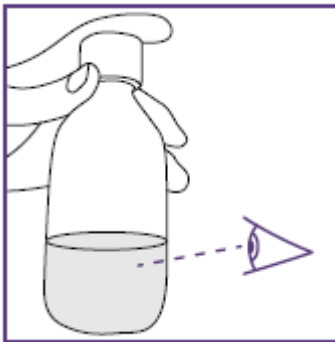
Cautionary Information:

Allow the suspension to adjust to room temperature if it has been stored in the refrigerator.



a. **Gently** shake the bottle for **at least 10 seconds** before each dose.

→ This is intended to provide a well-mixed suspension.



b. Check whether the suspension is mixed thoroughly, i.e.:

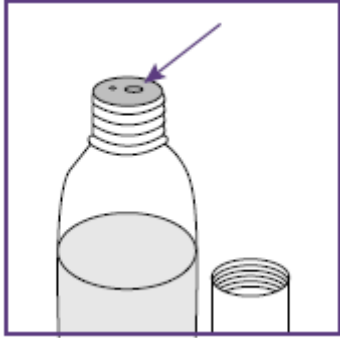
- no clumps
- no deposit.

c. **If there are clumps or deposit:**

Repeat steps a. and b.

d. Shaking can lead to formation of foam.

Let the bottle stand until the foam dissolves.



e. Unscrew the bottle cap, but keep the adapter on the top of the bottle.

Note:

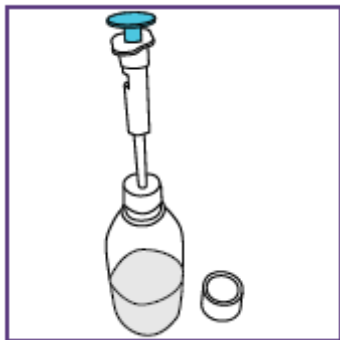
The larger opening visible on the adapter is used to connect the blue syringe.

The surface of the bottle adapter should be free of liquid.

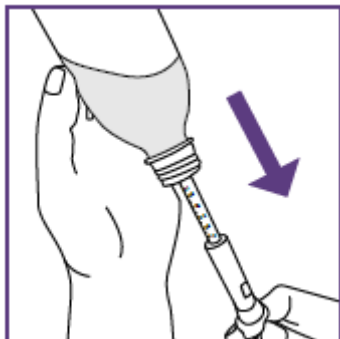
f. **If there is any liquid on the adapter:**

Remove the liquid with a clean tissue

Step 3.2: Extracting the required dose

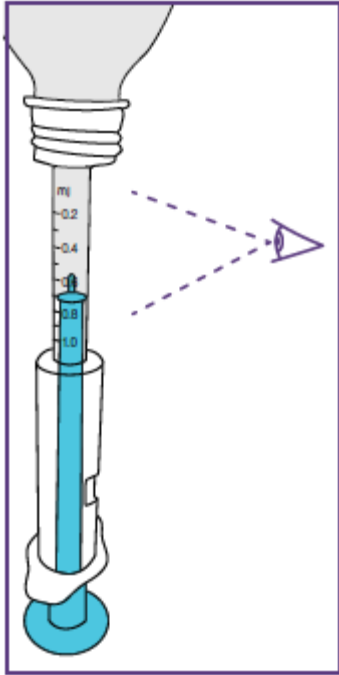


a. Keep the bottle in the upright position. Insert the tip of the blue syringe **fully** into the large opening of the adapter

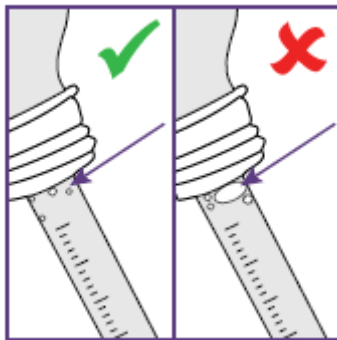


b. Turn the bottle upside down.

c. Pull the blue plunger rod **slowly** until it stops (i.e. until the set dose is reached).



d. Carefully check for air in the blue syringe.
Smaller air bubbles are not critical.

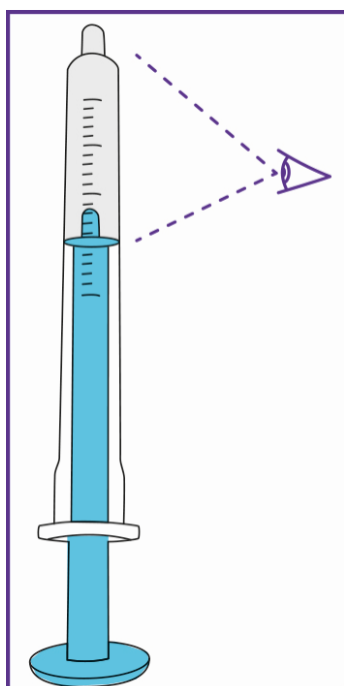


e. **If there are bigger air bubbles:**

- Return the suspension to the bottle by pushing back the plunger rod into the blue syringe as far as possible.
- Repeat steps b. to e.

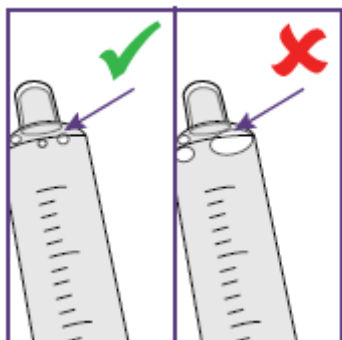
f. Return the bottle to the upright position.

g. Remove the blue syringe **carefully** from the adapter



h. Hold the blue syringe upright and check:

- that the tip of the blue syringe is filled
- whether the right dose has been filled into the blue syringe
- that no big air bubbles are present.



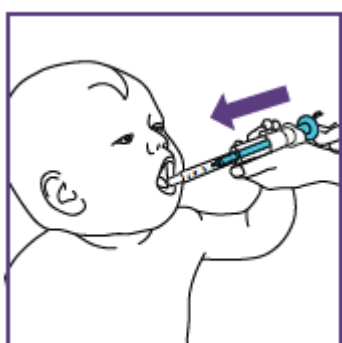
i. If there are bigger air bubbles or air in the tip:

- Insert the tip of the blue syringe again fully into the large opening of the adapter
- Return the suspension to the bottle by pushing back the plunger rod into the blue syringe as far as it goes.
- Repeat steps b. to h. until no bigger air bubbles are visible.

j. Close the bottle with the screw cap.

Administer the suspension immediately after filling the blue syringe (step 3.3)

Step 3.3: Administration of prescribed dose



- Place the blue syringe into the mouth of the patient.
- Direct its tip into the cheek to allow for natural swallowing.
- Push the plunger rod down **slowly** until the plunger stops (blue syringe is completely empty).
- Ensure that the patient swallows the entire dose.



Cautionary Information:

The patient must swallow the full dose of medicine.

If the dose repeatedly is not completely swallowed or if the patient is vomiting, consult your doctor for further instructions.



- Encourage the patient to drink one typical serving of liquid.
 - For an infant of 6 months, for example, this may be 20 mL.
 - This can also be breast-feeding.

4. Cleaning and storage

The blue syringe must be cleaned following every application.

Follow the steps listed below to clean the device. Altogether, **three** cycles of cleaning are necessary to ensure proper cleaning.

Before you start, you will need the following equipment for step 4.1:

- Get two containers (such as a cup or bowl)
 - one container filled with drinking water,
 - the other container empty

Step 4.1: Cleaning



- a. Dip the tip of the blue syringe into the container of water.
- b. Withdraw water until plunger rod stops.



- c. Empty the blue syringe into the prepared empty container

- d. Repeat steps a. to c. an **additional two times**.
- e. After cleaning, push the plunger rod back in until it stops.
- f. Dry the outer surface of the syringe with a clean tissue



Cautionary Information:

- Do not clean the blue syringe in the dish washer.
- Never boil the blue syringe.

Step 4.2: Storage

Store the blue syringe in a clean and dry place until next use, e.g. keep it in the box Xarelto was given to you.
Keep away from sunlight.



Cautionary Information:

The blue syringe can be used for up to 14 days.

Store the suspension below 30 °C.

**Cautionary Information:**

Do not freeze the suspension.

The prepared suspension is stable at room temperature for up to 14 days (preparation date plus 14 days).

Keep Xarelto out of the sight and reach of children.

Store the prepared suspension upright.

5. Disposal

Any unused medicine or waste material, syringes, and adapter should be disposed of in accordance with local requirements.

6. Damage/Malfunction

Any serious incidents that occur in connection with the product should be reported to the manufacturer and the relevant authority in your country.