



# Rivaroxaban following Fontan completion surgery

This leaflet is for parents and carers about how to use this medicine in children. Our information sometimes differs from that provided by the manufacturers, because their information is usually aimed at adults. Please read this leaflet carefully. Keep it somewhere safe so that you can read it again.



Do not stop giving rivaroxaban without talking to your child's health professional. Your child should have their Patient Alert Card with them at **all** times. Show it to anyone who treats them.

## Name of medicine

**Generic name:** Rivaroxaban

**Brand names** Xarelto

## Why is it important for my child to take this medicine?

Patients who have undergone Fontan completion surgery (also called total cavopulmonary connection) are at risk of developing blood clots, which may block veins or arteries. Rivaroxaban helps to stop blood clots from forming.

## What is rivaroxaban available as?

**Tablets:** 2.5 mg, 10 mg, 15 mg, 20 mg

**Granules:** these are provided with a bottle and syringes in a kit. Two different sizes are available: 50 mL and 100 mL bottles. The mixture, once made, contains 1 mg in each mL.

## When should I give rivaroxaban?

Rivaroxaban may be given **once or twice** each day depending on your child's weight. Your doctor will tell you how often to give it.

- **Once each day:** this can be in the morning or the evening.
- **Twice each day:** Give one dose in the morning and one in the evening. Ideally these times are 10–12 hours apart. For example, this could be between 7 and 8 am and between 7 and 8 pm.

Give the medicine at about the same time(s) each day so that this becomes part of your child's daily routine, which will help you to remember.

## How much should I give?

Your child's health professional will work out the amount of medicine (the dose) that is right for your child. The dose will be shown on the medicine label.

 It is vital that you follow your doctor's instructions about how much to give.

## How should I give it?

 Rivaroxaban tablets or granules should be given with food (or a milk feed), otherwise they may not work properly.



**Tablets** should be swallowed with a glass of water or juice/squash. Your child should not chew the tablets.

You can crush the tablet(s) and mix with water or apple puree. Your child should take it all straightaway, followed by some food or a milk feed.

**Granules:** These come in a bottle as a kit.

- The information leaflet with the medicine explains how to make the mixture and how to give it to your child. Read the instructions carefully and also watch the video to make sure you know what to do. If you are not sure, ask your pharmacist or nurse to explain.
- Tap the bottle to make sure the granules are not stuck to the sides.
- Using the larger (50 mL) syringe, add the right amount of water to the bottle (do not use fizzy water). The instructions will tell you how much water to add to make up the liquid.
- Put the lid on and shake the bottle for 1 minute.
- To give your child a dose, use the smaller blue syringe supplied with the medicine. Draw up the right amount of the mixture – this amount will be shown on the medicine label. Give this to your child straight away. Your child should then have a drink of normal size for them and some food (or a milk feed).
- Keep the bottle of mixture upright and out of the reach of children. It does not need to be kept in the fridge. It should only be kept for 14 days. Write the date that it expires on the label, to remind you.

## When should the medicine start to work?

The medicine will work straight away but you will not see any difference in your child.

## What if my child is sick (vomits)?

- If your child is sick less than 30 minutes after having a dose of rivaroxaban, give them the same dose again.
- If your child is sick more than 30 minutes after having a dose of rivaroxaban, you do not need to give them another dose. Wait until the next normal dose.
- If your child is sick again, seek advice from your health professional. They will decide what to do based on your child's condition and the medicine involved.

## What if I forget to give it?

**If you usually give it once a day:** If you remember up to 12 hours after you should have given the dose, give the missed dose. If you remember after this time, do not give the missed dose. Wait until the next dose as normal.

## What if I forget to give it?

If you usually give it twice a day

- If you forget the morning dose, you can give it when you remember or together with the evening dose.
- If you forget the evening dose, this can be given later in the same evening. Do not give the missing evening dose with the next morning dose.

## What if I think I have given too much?

If you think you may have given your child too much rivaroxaban, contact your doctor or local NHS services straight away (details at end of leaflet). Have the medicine packaging with you if you telephone for advice.

## Are there any possible side-effects?

We use medicines to make our children better, but they can sometimes cause effects that we don't want (side-effects).

### Side-effects you must do something about

 Rivaroxaban may cause some rare but serious side-effects. If you notice any of the following, take your child to hospital or call for an ambulance:

- Seizure (fit)
- Weakness on one side of the body
- Bleeding anywhere that won't stop, or if there is blood in their vomit or poo
- If your child is weak, tired, pale, feels dizzy, has a headache, develops swelling or is short of breath.

 If your child has swelling of the face, lips, mouth, tongue or throat, difficulty swallowing, difficulty breathing or suddenly feels light-headed (or faints), they may be allergic to rivaroxaban.

 If your child hits their head, watch them closely. If they become sleepy, get a lump on their head or has any bleeding, call an ambulance or take your child to hospital straight away.

### Other side-effects you need to know about

Your child may get the following side-effects when they first start taking rivaroxaban. They usually get better after about a week.

- They may get a fever (high temperature), have stomach ache, indigestion, feel or be sick, or get constipation or diarrhoea.
- Your child may get nose bleeds, bleeding gums, the veins in the whites of the eyes may become noticeable, or they may bruise more easily than usual.
- They may feel that their heart is beating quickly.
- They may get headaches.
- They may look pale and feel weak or short of breath.
- You may see blood in their urine (wee).
- They may get swelling or pain in their arms or legs.

- They may feel dizzy or faint when standing up.
- They may feel weaker and more tired than usual.
- They may get a rash or itchy skin.
- Girls may get heavy bleeding during their period.

There may sometimes be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your child's health professional.

## Can other medicines be given at the same time as rivaroxaban?

- You should not give your child ibuprofen.
- You can give your child medicines that contain paracetamol, unless your doctor has told you not to.
- Rivaroxaban should not be taken with some medicines that you get on prescription. Tell your doctor and pharmacist about any other medicines your child is taking before giving rivaroxaban. This includes herbal and complementary medicines.

## Is there anything else I need to know about this medicine?

-  Do not stop giving rivaroxaban without talking to your child's health professional first.
-  A Patient Alert Card is provided with the medicine. Your child should have this card with them at **all** times. Show it to anyone who is going to treat your child, include the dentist.
- Although your child is at risk of various side-effects while taking rivaroxaban, the risk of harm from not taking the medicine is greater than the risk of harm from side-effects.
- Other children may be taking rivaroxaban for different reasons and may need a different dose (amount) from your child. Follow the instructions on the medicine label.
- Girls who are sexually active should use contraception to prevent pregnancy, as rivaroxaban can harm a developing baby. If your daughter thinks she may be pregnant, she should contact her doctor straight away but continue to take rivaroxaban in the meantime.

## Where should I keep this medicine?

- Keep the medicine in a cupboard, away from heat and direct sunlight. It does not need to be kept in the fridge.
- Make sure children cannot see or reach the medicine.

## Who to contact for more information

Your doctor, pharmacist or nurse will be able to give you more information about rivaroxaban and other medicines used to treat blood clots. You can also get information from:

**England: NHS 111**  
Tel 111 [nhs.uk](https://www.nhs.uk)

**Wales: NHS 111 Wales**  
Tel 111 [111.wales.nhs.uk](https://www.111.wales.nhs.uk)

**Scotland: NHS 24**  
Tel 111 [nhs24.scot](https://www.nhs24.scot)

**Northern Ireland: NI Direct**  
[nidirect.gov.uk](https://www.nidirect.gov.uk)

[www.medicinesforchildren.org.uk](http://www.medicinesforchildren.org.uk)