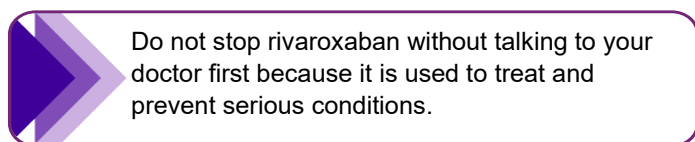


Rivaroxaban for the treatment and prevention of blood clots



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.



Name of medicine

Generic name: Rivaroxaban

Brand name: Xarelto

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

Blood clots can form in any part of the body. They may block blood vessels, leading to complications. Rivaroxaban is an anticoagulant – a medicine that is used to prevent blood clots from getting bigger and to reduce the risk of new blood clots forming.

Your child will be given injections of another anticoagulant called heparin for at least 5 days before they start taking rivaroxaban.


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: 100 mL and 250 mL bottles. The mixture, once made, contains 1 mg in each mL.

When should I give rivaroxaban?

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


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

- **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.
- **Three times each day:** These times should be 6–8 hours apart, depending on what time your child wakes up and goes to bed. For example, this could be between 6 and 7 am, between 12 and 2 pm, and between 9 and 10 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 doctor 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 important 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 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 tablet. You can crush the tablet(s) and mix it with water or apple puree. Your child should take it all straightaway, followed by some food or a feed.



Granules: These come in a bottle as a kit. Tap the bottle to make sure the granules are not stuck to the sides. Use the larger (50 mL) syringe to add right amount of water to the bottle (do not use fizzy water). This should be 50 mL if you have a 100 mL bottle, or 100 mL (two lots of 50 mL) if you have a 250 mL bottle. The instructions will tell you how much to add. Put the lid on and shake the bottle for 1 minute.

- To give your child a dose, use the smaller blue syringe to draw up the right amount of this mixture. The amount will be shown on the 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 feed).
- The information leaflet with the medicine explains how to make the mixture and how to give it to your child. The leaflet also provides a link to a video that you can watch. Read the instructions carefully and watch the video to make sure you know what to do. If you are not sure, ask your pharmacist or nurse to explain.
- 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 to throw it away.

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 doctor or pharmacist. 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.

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.

If you usually give it three times a day

Do not give the missed dose. Give the next dose as normal.

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 or packaging with you if you telephone for advice.

Are there any possible side-effects?

We use medicines to make our children better, but sometimes they 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. Take the medicine packaging with you.

- If your child has a severe lasting headache, vomiting (being sick), dizziness, or a seizure (fit), or they are less alert than normal or have a stiff neck, they may have bleeding in the brain.
- If your child is weak, tired, pale, feels dizzy, has a headache, develops swelling, is short of breath or has chest pain, they may have bleeding elsewhere in the body.
- If they have bleeding anyway that won't stop.
- If your child has swelling of the face, lips, mouth, tongue or throat, difficulty swallowing, a skin rash, difficulty breathing or suddenly feels light-headed (or faints), they may be allergic to rivaroxaban.

Other side-effects you need to know about

Your child may get the following side-effects when taking rivaroxaban.

- They may get a fever (high temperature), have stomach ache, indigestion, feel or be sick, or get constipation or diarrhoea.
- Your child may have a nose bleed, bleeding gums, bleeding from the whites of the eyes or they may bruise more easily than usual.
- They may get headache.
- They may look pale and feel weak or short of breath.
- They may see blood in the urine (wee).
- Your daughter may get heavy bleeding during her period.
- 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.

There may sometimes be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor. You can report any suspected side-effects to a UK safety scheme at mhra.gov.uk/yellowcard.

More information on side-effects can be found in a [leaflet](#) on our website.

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.
- Check with your doctor or pharmacist before giving any other medicines to your child. This includes herbal and complementary medicines.

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



Do not stop rivaroxaban without talking to your doctor first, because blood clots can cause serious issues.

- Although your child is at risk of some side-effects while taking rivaroxaban, the risk of harm from not taking the medicine is much greater than the risk of harm from side-effects.
- If your daughter is sexually active, she should use contraception to prevent pregnancy, as rivaroxaban can harm a developing baby. If she thinks she may be pregnant, she should contact your doctor straight away but continue to take rivaroxaban.

General advice about medicines

- Try to give medicines at about the same time(s) each day, to help you remember.
- If you are not sure a medicine is working, contact your doctor but continue to give the medicine as usual in the meantime.
- Only give this medicine to your child. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- If you think someone else may have taken the medicine by accident, contact a doctor straight away.
- Make sure that you always have enough medicine. Order a new prescription at least 2 weeks before you will run out.
- Make sure that the medicine you have at home has not reached the 'best before' or 'use by' date on the packaging. Give old medicines to your pharmacist to dispose of.

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 that children cannot see or reach the medicine.
- Keep the medicine in the container it came in.

Who to contact for more information

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

You can also get useful information from:

England: NHS 111

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

Scotland: NHS 24

Tel 111 [nhs24.scot](https://www.nhs24.scot)

Wales: NHS 111 Wales

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

Northern Ireland: NI Direct

nirect.gov.uk

www.medicinesforchildren.org.uk