



Pharmacy Department

Rivaroxaban (Xarelto) for the treatment of venous thromboembolism in children / young adults (<18 years)

Information for parents and carers

Your child has been prescribed a medicine called rivaroxaban. This leaflet aims to provide you with information, advice and guidance whilst your child is taking rivaroxaban. There is a lot of information, so keep this leaflet handy to refer to when you need it. If you have any queries or concerns, please speak to the doctor or nurse looking after your child.

What is rivaroxaban and what is it used for?

It is a type of medicine called an anticoagulant. These medications aim to prevent extension of an existing blood clot and reduce the risk of blood clots developing. At least 5 days of heparin treatment (another type of anticoagulant) should be given prior to starting rivaroxaban in children (heparin is given either directly into the vein – intravenous/IV or as an injection under the skin of the leg or tummy – subcutaneous/SC)

Why has rivaroxaban been prescribed?

Your child / young person has been diagnosed with a blood clot, Blood clots can happen in many different parts of the body. For example, those in the leg are often called a deep vein thrombosis (DVT), those in the lungs are called a pulmonary embolism (PE) and those in the brain are called a cerebral sinus thrombosis (CVST). Rivaroxaban is a treatment for this.

What are the benefits of taking rivaroxaban?

It reduces the risk of a worsening clot or new blood clots and the complications associated with these conditions. Rivaroxaban has been used for many years in adults, and recent studies have confirmed its effectiveness in children / young people.

How do I give rivaroxaban?

- It is best to have the medicine at the same time each day. If the doctor has advised you to give the rivaroxaban:
 - once a day – do this about 24 hours apart
 - twice a day – do this about 12 hours apart
 - three times a day – do this about eight hours apart.
- The doctor looking after your child will decide how much they need to take (the dose), how often and for how long. The dose and how often they need to take this medicine depends on their weight and may increase if they grow and gain weight during the time they are on rivaroxaban.



- Rivaroxaban should be given with food/milk feed. Your child / young person can eat any food and have any drink while they are taking this medicine.
- After each dose, your child should have a drink. Older children should have a small glass of water or milk (about 240ml), younger children should have a smaller amount (for example, a baby should have about 20ml)
- Your child / young person can take rivaroxaban as a liquid (oral suspension) or as tablets. We will prescribe what is most appropriate. They can be given the oral suspension through a tube into their nose (nasogastric) or into their tummy (gastric) if needed.
- If your child / young person spits out the dose or vomits less than 30 minutes after you have given them the rivaroxaban, give them another dose. If they vomit more than 30 minutes after you have given them the medicine, do not give them a new dose. Give them their next dose at the next scheduled time. Contact the doctor if they keep spitting up the dose or they vomit after you have given them the rivaroxaban.

What if I forget to give the rivaroxaban?

- It is very important that you give your child / young person the rivaroxaban as advised by their doctor. If they miss doses, their blood clot might get bigger or they may get new clots.
- If your child / young person has rivaroxaban once a day, give them the missed dose as soon as you remember on the same day. If this is not possible, skip this dose. Then give them their normal dose the day after. Do not give them more than one dose a day.
- If your child / young person has rivaroxaban twice a day:
 - Missed morning dose – give them the missed dose as soon as you remember. It is OK to give your child the missed morning dose together with the evening dose.
 - Missed evening dose – give them the missed dose in the same evening. Do not give two doses the next morning.
- If your child / young person has rivaroxaban three times a day: Do not make up for the missed dose. Give them their next dose at the planned time.

How long do they need to take rivaroxaban?

Most patients need to take rivaroxaban for three to six months. The doctor looking after your child / young person will decide how long they need to take rivaroxaban.

Who will prescribe the rivaroxaban?

The hospital team looking after your child will prescribe the medication, and your GP surgery may be able to take over this repeat prescription if the duration is longer than 3 months, under the direction of the hospital team.

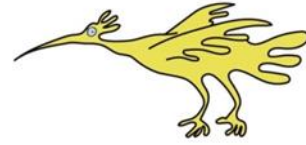
What are the risks of taking rivaroxaban?

Your child / young person will be at greater risk of bleeding. This is a possible side effect of taking any anticoagulant medication and it can sometimes be serious. Serious bleeding affects 1-3 people in every 100. They are more likely to bleed if injured when taking rivaroxaban; therefore, you must be aware that if your child cuts themselves they may bleed for a little longer than normal.

Seek medical help straight away if your child / young person has bleeding, especially if they have any of the following symptoms:

- coughing or vomiting blood
- black stools (poo) or blood in their stools

- severe, persistent headache, dizziness or weakness
- a fall or injury to their head or face: if your child suffers a head injury, hits concrete or a hard surface then you must take them to your local Accident and Emergency Department to be checked for internal bleeding.
- blood in their urine (wee)
- unexplained or severe bruising
- persistent nose bleeds
- other unexpected or uncontrollable bleeding.



There is no specific reversal agent for rivaroxaban which is licensed in children / young people currently, but there are medications/blood products that can be given to reverse some of the effects if there is significant bleeding. If you have any concerns about these risks, you can discuss them in more detail with the doctor, nurse or pharmacist.

Rivaroxaban can also cause other side effects such as dizziness and headaches in 1-10 people in every 100 taking it. If your child / young person has either of these symptoms, please tell the team looking after them. They may prescribe your child / young person a different anticoagulant.

Risks if your child / young person menstruates

Some children / young people have heavier and longer periods when taking rivaroxaban. If this happens, let your nurse or doctor know and they will decide on how best to manage this.

We do not know if rivaroxaban is safe during pregnancy. If your young person gets pregnant or plans to have a baby whilst on rivaroxaban, please tell the doctor looking after them straight away.

Are there any alternatives?

Your child / young person may be able to take a different anticoagulant medicine. Your clinician will discuss these with you, if appropriate.

Will my child / young person need blood tests when taking rivaroxaban?

They will need to have a blood test before starting rivaroxaban to check their kidney and liver function, which will need to be checked again if they remain on it for more than 3 months. Their clinician may decide they need have other specialist blood tests as well. Rivaroxaban does not require regular monitoring of drug levels with blood tests (unlike warfarin and heparin).

Can they take other medicines with rivaroxaban?

It is important to let the clinician who prescribes rivaroxaban know all the other medicines your child / young person is taking. This includes any medicines you have bought for them over the counter without a prescription, because these might affect how rivaroxaban works.

If your child / young person starts a new medicine, please tell the prescribing clinician that they are taking rivaroxaban. If you are unsure about whether your child / young person can take another medicine with rivaroxaban, please ask your clinician for advice.

What else do I need to know when giving my child / young person rivaroxaban?

They have a greater risk of bleeding. They must not take part in any contact sports, for example, rugby, mixed martial arts etc, due to the risk of head injury or trauma to internal organs. They can however take part in a variety of other sports and do PE. Please ask your child's / young person's doctor for advice on this.

Please tell their doctor or dentist that your child / young person is taking rivaroxaban if they have any type of surgery or dental work. This is so they can reduce the risk of bleeding. They may need to stop taking the medicine for a short while if it is safe to do so.

Does rivaroxaban have an expiry date?

Do not use this medicine after the expiry date, which is shown on the carton and on the oral suspension bottle after the letters 'EXP'. The expiry date shows the last day of that month.

How do I store rivaroxaban oral suspension?

You can keep the oral suspension for up to 14 days at room temperature after you have made it up. Store the prepared suspension upright, do not store above 30 °C and do not freeze. Do not put the medicine down the sink or toilet or into your household waste. Ask your pharmacist for advice on how to throw away medicines you no longer use.

General advice about medicines

- 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 cause harm.
- If you think someone else may have taken the medicine by accident, contact your doctor straight away.
- Make sure that you always have enough medicine. Order a new prescription from the hospital team looking after your child or GP surgery 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.
- This leaflet should be read with any manufacturers' patient information. You must always discuss individual treatment with the appropriate member of staff.

Who can I contact with queries and concerns?

If you have any questions about your medication whilst you are in hospital, please do not hesitate to ask one of the Pharmacy team, alternatively you can telephone us on 0151 252 5311.

This leaflet only gives general information. You must always discuss the individual treatment of your child with the appropriate member of staff. Do not rely on this leaflet alone for information about your child's treatment.

This information can be made available in other languages and formats if requested.

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How can you find out more about DVT and PE?

The Thrombosis UK website also has more information: www.thrombosisuk.org/



References:

Addendum to British Society for Haematology guideline on the investigation, management and prevention of venous thrombosis in children (Br. J. Haematol. 2011; 154: 196–207) - Biss - British Journal of Haematology - Wiley Online Library. July 2021.

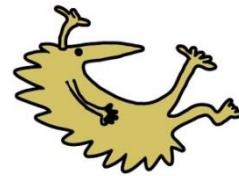
SmPC Xarelto film-coated tablets/granules for oral suspension

[Xarelto 1 mg/mL granules for oral suspension - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

[Xarelto 15mg film-coated tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

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