

Package leaflet: Information for the user

Rivaroxaban 15 mg Film-coated Tablets

Rivaroxaban 20 mg Film-coated Tablets

rivaroxaban

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rivaroxaban is and what it is used for
2. What you need to know before you take Rivaroxaban
3. How to take Rivaroxaban
4. Possible side effects
5. How to store Rivaroxaban
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1. What Rivaroxaban is and what it is used for

Rivaroxaban Tablets contain the active substance rivaroxaban.

This medicine is used in adults to:

- prevent blood clots in the brain (stroke) and other blood vessels in your body if you have a form of irregular heart rhythm called non-valvular atrial fibrillation.
- treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent such blood clots from re-occurring.

This medicine is used in children and adolescents below 18 years and with a body weight of 30 kg or more to:

- treat and prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs, after having had initial treatment of at least 5 days with injectable medicines used to treat blood clots.

Rivaroxaban belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and so reducing the risk of blood clots.

2. What you need to know before you take Rivaroxaban

Do not take Rivaroxaban

- if you are allergic to rivaroxaban or any of the other ingredients of this medicine (listed in section 6)
- if you are bleeding excessively
- if you have a disease or condition in an organ of the body that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- if you are taking medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), except:
 - when changing anticoagulant treatment or
 - while getting heparin through a venous or arterial line to keep it open.
- if you have a liver disease which leads to an increased risk of bleeding
- if you are pregnant or are breast-feeding.

Do not take Rivaroxaban and tell your doctor if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rivaroxaban:

- if you have an increased risk of bleeding, as could be the case in situations such as:
 - if you have severe kidney disease in adults, and moderate or severe kidney disease in children and adolescents, as your kidney function may affect the amount of medicine that works in your body
 - if you have a bleeding disorder
 - if you have very high blood pressure, not controlled by medical treatment
 - if you have diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or inflammation of the oesophagus (food pipe) e.g. due to gastroesophageal reflux disease (disease where stomach acid goes upwards into the food pipe (oesophagus)) or tumours located in the stomach or bowels or genital tract or urinary tract
 - if you have a problem with the blood vessels in the back of your eyes (retinopathy)
 - if you have a lung disease where your air passages (bronchi) are widened and filled with pus (bronchiectasis), or you have had previous bleeding from your lung
- if you have a prosthetic heart valve
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor who will decide if the treatment may need to be changed.
- if your doctor finds that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.

If any of the above apply to you, tell your doctor before you take Rivaroxaban. Your doctor will decide if you should be treated with this medicine and if you should be kept under closer observation.

If you need to have an operation

- It is very important to take Rivaroxaban before and after the operation exactly at the times you have been told by your doctor.
- If your operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):
 - It is very important to take rivaroxaban before and after the injection or removal of the catheter exactly at the times you have been told by your doctor.
 - Tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care will be needed.

Children and adolescents

Rivaroxaban tablets are **not recommended for children or adolescents with a body weight below 30 kg**. There is not enough information on the use of rivaroxaban in this group of children and adolescents in the same way as it is used to treat adults.

Other medicines and rivaroxaban

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking any of the medicines below, **tell your doctor before** taking rivaroxaban, because the effect of rivaroxaban may be increased. Your doctor will decide if you should be treated with this medicine and if you should be kept under closer observation.

- medicines for fungal infections (e.g. fluconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin
- ketoconazole tablets (used to treat Cushing's syndrome - when the body produces an excess of cortisol)

- medicines for bacterial infections (e.g. clarithromycin, erythromycin)
- anti-viral medicines for HIV/AIDS (e.g. ritonavir)
- other medicines to reduce blood clotting (e.g. enoxaparin, clopidogrel or vitamin K antagonists such as warfarin and acenocoumarol)
- anti-inflammatory and pain relieving medicines (e.g. naproxen or aspirin/acetylsalicylic acid)
- dronedarone, a medicine to treat abnormal heartbeat
- medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)).

If you are taking any of the medicines below, **tell your doctor before** taking rivaroxaban, because the effect of rivaroxaban may be reduced. Your doctor will decide if you should be treated with rivaroxaban and if you should be kept under closer observation.

- some medicines for treatment of epilepsy (phenytoin, carbamazepine, phenobarbital)
- St John's Wort (*Hypericum perforatum*), a herbal product used for depression
- rifampicin, an antibiotic.

If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, they may also prescribe a medicine to prevent such ulcers.

Pregnancy and breast-feeding

Do not take rivaroxaban if you are pregnant or breast-feeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking this medicine. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines

Rivaroxaban may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4 Possible side effects). If you experience these side effects, do not drive, ride a bicycle or use any tools or machines.

Rivaroxaban contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet and so is essentially "sodium-free".

3. How to take Rivaroxaban

Taking your medicine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You must take Rivaroxaban together with a meal.
Swallow the tablet(s) preferably with water.

For adults with difficulty swallowing the tablet whole, talk to your doctor about other ways to take rivaroxaban. The tablet may be crushed and mixed with water or apple puree immediately before you take it. Take some food after taking this mixture.

If necessary, your doctor may also give you the crushed Rivaroxaban tablet through a stomach tube.

For children and adolescents who are unable to swallow tablets whole, please use rivaroxaban granules for oral suspension. If the oral suspension is not available, you may crush the tablet and mix with water or apple puree immediately before taking. Take some food after taking this mixture.

If necessary, your doctor may also give you the crushed Rivaroxaban tablet through a stomach tube.

When to take Rivaroxaban

Take the tablets every day until your doctor tells you to stop.

Take the tablets every day at approximately the same time. Consider setting an alarm to remind you. Your doctor will decide how long you must continue treatment.

If your heart beat needs to be restored to normal by a procedure called cardioversion, take rivaroxaban at the times your doctor tells you.

How much to take

Adults aged 18 years and above

- **To prevent blood clots in brain (stroke) and other blood vessels in your body**

The recommended dose is one Rivaroxaban 20 mg Tablet once a day.

If you have kidney problems, the dose may be reduced to one Rivaroxaban 15 mg Tablet once a day.

If you need a procedure to treat blocked blood vessels in your heart (called a percutaneous coronary intervention - PCI with an insertion of a stent), your doctor may reduce the dose to one Rivaroxaban 15 mg Tablet once a day (or to one Rivaroxaban 10 mg Tablet once a day in case your kidneys are not working properly) in addition to an antiplatelet medicine such as clopidogrel.

- **To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs, and to prevent blood clots from re-occurring**

For the first three weeks, the recommended dose is one Rivaroxaban 15 mg Tablet twice a day. After three weeks, the recommended dose is one Rivaroxaban 20 mg Tablet once a day. After at least six months of blood clot treatment, your doctor may decide to continue treatment with either one 10 mg tablet or one 20 mg tablet once a day.

If you have kidney problems and take 20 mg of rivaroxaban once a day, your doctor may decide to reduce the dose after 3 weeks to 15 mg rivaroxaban once a day, if the risk for bleeding is greater than the risk for having another blood clot.

Children and adolescents

The dose of rivaroxaban depends on the body weight and will be calculated by the doctor.

- **Children and adolescents with a body weight between 30 kg and less than 50 kg:** The recommended dose is one Rivaroxaban 15 mg Tablet once a day.
- **Children and adolescents with a body weight of 50 kg or more:** The recommended dose is one Rivaroxaban 20 mg Tablet once a day.

As the rivaroxaban dose is based on body weight it is important to keep scheduled doctor's visits because the dose may need to be adjusted as the weight changes.

Never adjust the dose of rivaroxaban by yourself. The doctor will adjust the dose if necessary.

Do not split the tablet in an attempt to provide a fraction of a tablet dose. If a lower dose is required, please use rivaroxaban granules for oral suspension.

If you spit up the dose or vomit

- less than 30 minutes after you have taken rivaroxaban, take a new dose.
- more than 30 minutes after you have taken rivaroxaban, **do not** take a new dose. In this case, take the next rivaroxaban dose at the usual time.

Contact the doctor if you repeatedly spit up the dose or vomit after taking rivaroxaban.

If you forget to take rivaroxaban

Adults, children and adolescents:

If you are taking one 20 mg tablet or one 15 mg tablet **once a day** and have missed a dose, take it as soon as you remember. Do not take more than one tablet in a single day to make up for a forgotten dose. Take the next tablet on the following day and then carry on taking one tablet once a day.

Adults:

If you are taking one 15 mg tablet **twice a day** and have missed a dose, take it as soon as you remember. In this case you can take two 15 mg tablets at the same time to get a total of two tablets (30 mg) on one day. On the following day you should carry on taking one 15 mg tablet twice a day. Do not take more than two 15 mg tablets in a single day.

If you take more rivaroxaban than you should

Contact your doctor immediately if you have taken too many tablets. Taking too much rivaroxaban increases the risk of bleeding.

If you stop taking rivaroxaban

Do not stop taking this medicine without talking to your doctor first, because rivaroxaban treats and prevents serious conditions.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, rivaroxaban can cause side effects, although not everybody gets them.

Like other similar medicines to reduce the formation of blood clots, rivaroxaban may cause bleeding which may potentially be life threatening. Excessive bleeding may lead to a sudden drop in blood pressure (shock). In some cases, the bleeding may not be obvious.

Tell your doctor IMMEDIATELY if you or the child experience any of the following side effects:

Signs of bleeding

- bleeding into the brain or inside the skull (symptoms can include headache, one-sided weakness, vomiting, seizures, decreased level of consciousness, and neck stiffness). This is a serious medical emergency. **Seek medical attention immediately!**
- bleeding more and for longer
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris (pain from not enough blood flowing to the heart).

Your doctor may decide to keep you under closer observation or change the treatment.

Signs of severe skin reactions

- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis).
- a drug reaction that causes rash, fever, inflammation of internal organs, blood abnormalities and systemic illness (DRESS syndrome).

The frequency of these side effects is very rare (up to 1 in 10,000 people).

Signs of severe allergic reactions

- swelling of the face, lips, mouth, tongue or throat (angioedema and allergic oedema); difficulty swallowing; hives (red, itchy, and swollen areas (welts) on the skin) and breathing difficulties (anaphylactic reactions), sudden drop in blood pressure (anaphylactic shock).

The frequency of anaphylactic reactions, including anaphylactic shock, is very rare (affecting up to 1 in 10,000 people). The frequency of angioedema and allergic oedema is uncommon (affecting up to 1 in 100 people).

Overall possible side effects.

Tell your doctor or pharmacist if you get any of the following side effects or any side effects not listed.

Common (may affect up to 1 in 10 people)

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- bleeding in the stomach or bowel, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nose bleed, bleeding in the gum
- bleeding into the eye (including bleeding from the whites of the eyes)
- bleeding into tissue or a cavity of the body (haematoma, bruising)
- coughing up blood
- bleeding from the skin or under the skin
- bleeding after an operation
- oozing of blood or fluid from surgical wound
- swelling in the limbs
- pain in the limbs
- reduced kidney function (may be seen in tests performed by your doctor)
- fever
- stomach ache, indigestion, feeling or being sick, constipation, diarrhoea
- low blood pressure (symptoms may be feeling dizzy or fainting when standing up)
- decreased general strength and energy (weakness, tiredness), headache, dizziness
- rash, itchy skin
- blood tests may show an increase in some liver enzymes

Uncommon (may affect up to 1 in 100 people)

- bleeding into the brain or inside the skull (see above, signs of bleeding)
- bleeding into a joint, causing pain and swelling
- low number of platelets, which are cells that help blood to clot (thrombocytopenia)
- allergic reactions, including allergic skin reactions and hives (see above, signs of severe allergic reactions)
- reduced liver function (may be seen in tests performed by your doctor)
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets
- fainting
- feeling unwell
- faster heartbeat
- dry mouth

Rare (may affect up to 1 in 1,000 people)

- bleeding into a muscle
- cholestasis (decreased bile flow), inflamed liver including (hepatitis), liver injury (hepatocellular injury)
- yellowing of the skin and eyes (jaundice)
- localised swelling
- collection of blood (haematoma) in the groin as a complication of the cardiac procedure where a catheter is inserted in your leg artery (pseudoaneurysm)

Very rare (may affect up to 1 in 10,000 people)

- accumulation of eosinophils, a type of white granulocytic blood cells that cause inflammation in the lung (eosinophilic pneumonia)

Frequency not known (frequency cannot be estimated from the available data)

- kidney failure after severe bleeding
- bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy)
- increased pressure within muscles of the legs or arms after bleeding, which leads to pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after bleeding)

Side effects in children and adolescents

In general, the side effects observed in children and adolescents treated with rivaroxaban are similar in type to those observed in adults and are mainly mild to moderate in severity.

Side effects that are observed more often in children and adolescents include:

Very common (may affect more than 1 in 10 people)

- headache
- fever
- nose bleeding
- being sick (vomiting)

Common (may affect up to 1 in 10 people)

- raised heartbeat
- blood tests may show an increase in bilirubin (bile pigment)
- thrombocytopenia (low number of platelets which are cells that help blood to clot)
- heavy menstrual bleeding

Uncommon (may affect up to 1 in 100 people)

- blood tests may show an increase in a subcategory of bilirubin (direct bilirubin, bile pigment)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Rivaroxaban

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on each blister or bottle after EXP.

The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Crushed tablets

Crushed tablets are stable in water or apple puree for up to 4 hours.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rivaroxaban Film-coated Tablets contain

The active substance is rivaroxaban. Each tablet contains 15 mg or 20 mg of rivaroxaban. The other ingredients are: Tablet core: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulfate, colloidal anhydrous silica and magnesium stearate.
Tablet film coat: hypromellose, iron oxide red, titanium dioxide and macrogol.

What Rivaroxaban looks like and contents of the pack

Rivaroxaban 15 mg Film-coated Tablets are red, round shaped, biconvex, film-coated tablets (approximately 5.6 mm in diameter), debossed with “C4” on one side and plain on other side.

They come in blisters of 10, 14, 28, 42 or 98 film-coated tablets or in bottles of 30, 100 or 500 film-coated tablets.

Rivaroxaban 20 mg Film-coated Tablets are brown-red, round shaped, biconvex, film-coated tablets (approximately 6.1 mm in diameter), debossed with “C3” on one side and plain on other side.

They come in blisters of 10, 14, 28 or 98 film-coated tablets or in bottles of 30, 100 or 500 film-coated tablets.

Not all pack sizes may be marketed.

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If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact medinfo@celixpharma.com.

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