

Package leaflet: Information for the user

Rivaroxaban 2.5 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 2.5 mg Tablets are and what they are used for
2. What you need to know before you take Rivaroxaban 2.5 mg Tablets
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1. What Rivaroxaban 2.5 mg Tablets are and what they are used for

You have been given Rivaroxaban because

- you have been diagnosed with an acute coronary syndrome (a group of conditions that includes heart attack and unstable angina, a severe type of chest pain) and have been shown to have had an increase in certain cardiac blood tests.

Rivaroxaban reduces the risk in adults of having another heart attack or reduces the risk of dying from a disease related to your heart or your blood vessels.

This medicine will not be given to you on its own. Your doctor will also tell you to take either:

- acetylsalicylic acid (aspirin) or
 - acetylsalicylic acid (aspirin) plus clopidogrel or ticlopidine.
- Or you have been given Rivaroxaban because you have been diagnosed with a high risk of getting a blood clot due to a coronary artery disease or peripheral artery disease which causes symptoms.

Rivaroxaban reduces the risk in adults of getting blood clots (atherothrombotic events). This medicine will not be given to you on its own. Your doctor will also tell you to take acetylsalicylic acid (aspirin).

In some cases, if you get rivaroxaban after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take in addition to acetylsalicylic acid (aspirin) for a short while.

Rivaroxaban tablets contains the active substance rivaroxaban and belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

2. What you need to know before you take Rivaroxaban 2.5 mg Tablets

Do not take Rivaroxaban 2.5 mg Tablets

- 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 an acute coronary syndrome and previously had bleeding or a blood clot in your brain (stroke)
- if you have coronary artery disease or peripheral artery disease and previously had bleeding in your brain (stroke) or where there was a blockage of the small arteries providing blood to the brain's deep tissues (lacunar stroke) or if you had a blood clot in your brain (ischaemic, non-lacunar stroke) in the previous month
- if you have a liver disease which leads to an increased risk of bleeding
- if you are pregnant or breast-feeding

Do not take Rivaroxaban 2.5 mg Tablets and tell your doctor if any of these apply to you.

Warnings and precautions

Rivaroxaban should not be used in combination with certain other medicines which reduce blood clotting such as prasugrel or ticagrelor other than acetylsalicylic acid and clopidogrel/ticlopidine.

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, as your kidney function may affect the amount of medicine that works in your body
 - if you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open (see section "Other medicines and Rivaroxaban 2.5 mg Tablets")
 - 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 are older than 75 years
- if you weigh less than 60 kg
- if you have a coronary artery disease with severe symptomatic heart failure
- 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 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 this medicine 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 2.5 mg Tablets are **not recommended for people under 18 years of age**. There is not enough information on their use in children and adolescents.

Other medicines and Rivaroxaban 2.5 mg Tablets

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 this medicine, 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, prasugrel and ticagrelor (see section "Warnings and Precautions"))
- anti-inflammatory and pain relieving medicines (e.g. naproxen or acetylsalicylic acid/aspirin)
- dronedarone, a medicine to treat abnormal heart beat
- 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 this medicine, 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.

- 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, he may also use a preventative ulcer treatment.

Pregnancy and breast-feeding

Do not take this medicine 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 rivaroxaban. 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

This medicine 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 2.5 mg Tablets contain 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 2.5 mg Tablets

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

Taking your medicine

The recommended dose is one 2.5 mg tablet twice a day.

This medicine can be taken with or without food.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take this medicine. The tablet may be crushed and mixed with water or apple puree immediately before you take it. If necessary, your doctor may also give you the crushed tablet through a stomach tube.

Rivaroxaban 2.5 mg Tablets will not be given to you on its own. Your doctor will also tell you to take acetylsalicylic acid (aspirin).

If you get rivaroxaban after an acute coronary syndrome, your doctor may tell you to also take clopidogrel or ticlopidine.

If you get rivaroxaban after a procedure to open a narrowed or closed artery of your leg to restore blood flow, your doctor may also prescribe clopidogrel for you to take in addition to acetylsalicylic acid (aspirin) for a short while.

Your doctor will tell you how much of these to take (usually between 75 to 100 mg acetylsalicylic acid (aspirin) daily or a daily dose of 75 to 100 mg acetylsalicylic acid (aspirin) plus a daily dose of either 75 mg clopidogrel or a standard daily dose of ticlopidine).

When to take Rivaroxaban

Take this medicine around the same time every day (for example, one tablet in the morning and one in the evening).

When to start Rivaroxaban 2.5 mg Tablets

Treatment with this medicine after an acute coronary syndrome should be started as soon as possible after your condition has stabilised at the earliest 24 hours after admission to hospital and at the time when anticoagulation treatment via injection would normally be stopped.

Your doctor will tell you when to start treatment with rivaroxaban if you have been diagnosed with coronary artery disease or peripheral artery disease.

Your doctor will decide how long you must continue treatment.

If you take more Rivaroxaban 2.5 mg Tablets than you should

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

If you forget to take Rivaroxaban 2.5 mg Tablets

Do not take a double dose to make up for a missed dose. If you miss a dose, take your next dose at the usual time.

If you stop taking Rivaroxaban 2.5 mg Tablets

Take this medicine on a regular basis and for as long as your doctor keeps prescribing it.

Do not stop taking this medicine without talking to your doctor first. If you stop taking this medicine, it may increase your risk of having another heart attack or stroke or dying from a disease related to your heart or your blood vessels.

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 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 list of possible side effects

Talk to 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)

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 2.5 mg Tablets

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 2.5 mg Tablets contain

- The active substance is rivaroxaban. Each tablet contains 2.5 mg of rivaroxaban.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulfate, colloidal anhydrous, silica, magnesium stearate, iron oxide yellow, titanium dioxide and macrogol.

What Rivaroxaban 2.5 mg Tablets look like and contents of the pack

Rivaroxaban 2.5 mg Tablets are light-yellow, round shaped, biconvex (approximately 6.1 mm in diameter), debossed with “C7” on one side and plain on other side.

They come in blisters of 14, 20, 28, 30, 56, 60, 98, 168 or 196 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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