

ROXAVID FILM COATED TABLETS

Rivaroxaban 15mg and 20mg

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What ROXAVID 15MG & 20MG is used for

ROXAVID 15MG & 20MG is used in adults to:

- prevention of blood clots in 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 blood clots from re-occurring in the blood vessels of your legs and/or lungs.

ROXAVID 15MG & 20MG is used in children and adolescents below 18 years and with a body weight of 30kg or more to:

- treat blood clots and prevent reoccurrence of blood clots in the veins or in the blood vessels of the lungs, following initial treatment of at least 5 days with injectable medicines used to treat blood clots.

How ROXAVID 15MG & 20MG works

ROXAVID 15MG & 20MG 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.

Before you use ROXAVID 15MG & 20MG

When you must not use it

Do not take ROXAVID 15MG & 20MG

- if you are allergic to rivaroxaban or any of the other ingredients of this medicine
- 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 breast-feeding

Do not take ROXAVID 15MG & 20MG and tell your doctor if any of these apply to you.

Before you start to use it

Warnings and precautions

Talk to your doctor or pharmacist before taking ROXAVID 15MG & 20MG.

Take special care with ROXAVID 15MG & 20MG

- if you have an increased risk of bleeding, as could be the case in situations such as:
 - severe kidney disease, since 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 "Taking other medicines")
 - bleeding disorders
 - very high blood pressure, not controlled by medical treatment
 - diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or inflammation of the oesophagus (gullet), e.g. due to

gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus)

- a problem with the blood vessels in the back of your eyes (retinopathy)
- a lung disease where your bronchi are widened and filled with pus (bronchiectasis), or 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 determines 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 ROXAVID 15MG & 20MG. 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 ROXAVID 15MG & 20MG 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 ROXAVID 15MG & 20MG 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 is necessary.

Children and adolescents

ROXAVID 15MG & 20MG tablets **are not recommended for children with a body weight below 30kg.** There is not enough information on its use in children and adolescents in the adult indications.

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- Taking other medicines

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

- some 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)
- some medicines for bacterial infections (e.g. clarithromycin, erythromycin)
- some 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)
- dronedarone, a medicine to treat abnormal heart beat
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs))

If any of the above apply to you, tell your doctor before taking ROXAVID 15MG & 20MG, because the effect of ROXAVID 15MG & 20MG may be increased. Your doctor will decide, if you should be treated with this medicine and if you should be kept under closer observation.

If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, he may also use a preventative ulcer treatment.

If you are taking

- 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 any of the above apply to you, tell your doctor before taking ROXAVID 15MG & 20MG, because the effect of ROXAVID 15MG & 20MG may be reduced. Your doctor will decide, if you should be treated with ROXAVID 15MG & 20MG and if you should be kept under closer observation.

Pregnancy and breastfeeding

Do not use ROXAVID 15MG & 20MG if you are pregnant or breastfeeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking ROXAVID 15MG & 20MG. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

ROXAVID 15MG & 20MG 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, that is to say essentially 'sodium-free'.

How to use ROXAVID 15MG & 20MG

- How much to use

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

Adults

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

- The recommended dose is one tablet ROXAVID 15MG & 20MG 20 mg once a day. If you have kidney problems, the dose may be reduced to one tablet ROXAVID 15MG & 20MG 15 mg once a day.

To treat blood clots in the veins of your legs and blood clots in the blood vessels of your lungs, and for preventing blood clots from re-occurring.

- The recommended dose is one tablet ROXAVID 15MG & 20MG 15 mg twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet ROXAVID 15MG & 20MG 20 mg once a day.
- After at least 6 months blood clot treatment your doctor may decide to continue treatment with either one 10 mg tablet once a day or one 20 mg tablet once a day.
- If you have kidney problems and take one tablet ROXAVID 15MG & 20MG 20 mg once a day, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet ROXAVID 15MG & 20MG 15 mg once a day if the risk for bleeding is greater than the risk for having another blood clot. Children and adolescents

The dose of ROXAVID 15MG & 20MG depends on the body weight and will be calculated by the doctor.

- The recommended dose for children and adolescents with a **body weight between 30 kg and less than 50 kg** is one **ROXAVID 15MG & 20MG 15 mg tablet** once a day.
- The recommended dose for children and adolescents with a **body weight of 50 kg or more** is one **ROXAVID 15MG & 20MG 20 mg tablet** once a day.

Take each ROXAVID 15MG & 20MG dose with a drink (e.g. water or juice) during a meal. Take the tablets every day at approximately the same time. Consider setting an alarm to remind you. For parents or caregivers: please observe the child to ensure the full dose is taken.

As the ROXAVID 15MG & 20MG 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 ROXAVID 15MG & 20MG 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 alternative presentations such as

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granules for oral suspension.

For children and adolescents who are unable to swallow tablets whole, please use other suitable pharmaceutical forms such as granules for oral suspension.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take ROXAVID 15MG & 20MG. The tablet may be crushed and mix with water or apple puree immediately before you take it. taking. If necessary, your doctor may also give the crushed ROXAVID 15MG & 20MG tablet through a stomach tube.

If you spit up the dose or vomit

- less than 30 minutes after you have taken ROXAVID 15MG & 20MG, take a new dose.
- more than 30 minutes after you have taken ROXAVID 15MG & 20MG, **do not** take a new dose. In this case, take the next ROXAVID 15MG & 20MG dose at the usual time.

Contact the doctor if you repeatedly spit up the dose or vomit after taking ROXAVID 15MG & 20MG.

- When to use it

Take the tablet every day until your doctor tells you to stop. Try to take the tablet at the same time every day to help you to remember it. Your doctor will decide how long you must continue treatment.

- How long to use it

Do not stop taking ROXAVID 15MG & 20MG without talking to your doctor first, because ROXAVID 15MG & 20MG treats and prevents serious conditions. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

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. Do not take more than two 15 mg tablets in a single day. If you forget to take a dose 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.

- If you use too much (overdose)

Contact your doctor immediately if you have taken too many ROXAVID 15MG & 20MG tablets. Taking too much ROXAVID 15MG & 20MG increases the risk of bleeding.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists, and pharmacists treating you that you are taking ROXAVID 15MG & 20MG.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking your medicines unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give ROXAVID 15MG & 20MG to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

Driving and using machines

ROXAVID 15MG & 20MG may cause dizziness (common side effect) or fainting (uncommon side effect). You should not drive or use machines if you are affected by these symptoms.

Side effects

Like all medicines, ROXAVID 15MG & 20MG can cause side effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), ROXAVID

15MG & 20MG 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.

Possible side effects which may be a sign of bleeding

Tell your doctor immediately if you experience any of the following side effects:

- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris, which may be signs of bleeding.

Your doctor may decide to keep you under closer observation or change how you should be treated.

Possible side effects which may be a sign of severe skin reaction

Tell your doctor immediately if you experience skin reactions such as:

- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis). The frequency of this side effect is very rare (up to 1 in 10,000).
- a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome). The frequency of this side effect is very rare (up to 1 in 10,000).

Possible side effects which may be a sign of severe allergic reactions

Tell your doctor immediately if you experience any of the following side effects:

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties; sudden drop in blood pressure. The frequencies of these side effects are very rare (anaphylactic reactions, including anaphylactic shock; may affect up to 1 in 10,000 people) and uncommon (angioedema and allergic oedema; may affect up to 1 in 100 people).

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Overall list of possible side effects

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), nosebleed, 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 following an operation
- oozing of blood or fluid from surgical wound
- swelling in the limbs
- pain in the limbs
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever
- stomachache, 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
- bleeding into a joint causing pain and swelling
- thrombocytopenia (low number of platelets, which are cells that help blood to clot)
- allergic reactions, including allergic skin reactions
- impaired function of the liver (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
- hives

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

- bleeding into a muscle
- cholestasis (decreased bile flow), hepatitis incl. hepatocellular injury (inflamed liver incl. liver injury)
- yellowing of the skin and eye (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)

Not known (frequency cannot be estimated from the available data)

- kidney failure after a severe bleeding
- increased pressure within muscles of the legs or arms after a bleeding, which leads to pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after a bleeding)

Side effects in children and adolescents

In general, the side effects observed in children and adolescents treated with ROXAVID 15MG & 20MG were similar in type to those observed in adults and were primarily mild to moderate in severity.

Side effects that were observed more often in children and adolescents:

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

- headache
- fever
- nose bleeding
- 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)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ROXAVID 15MG & 20MG

- Storage

Keep out of the reach and sight of children. Do not store above 30 °C.

Crushed tablets

Crushed tablets are stable in water or apple puree for up to 2 hours.

- Disposal

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

Product description

- What it looks like

ROXAVID 15: Rivaroxaban Film Coated Tablets Ph. Eur. 15 mg are Maroon, circular, biconvex film coated tablets debossed with “125” on one side and “15” on other side.

ROXAVID 20: Rivaroxaban Film Coated Tablets Ph. Eur. 20 mg are Dark Maroon, circular, biconvex film coated tablets debossed with “126” on

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one side and “20” on other side.

- Ingredients

Active

ingredient:

Rivaroxaban Ph. Eur

Inactive ingredients:

Microcelac 100, Lactose, Sodium Lauryl Sulfate, Croscarmellose sodium, Magnesium stearate, Opadry 04F565024 Brown (ROXAVID 15 mg), Opadry 04F565025 Brown (ROXAVID 20 mg) and Purified water.

- MAL number

Roxavid Film Coated Tablets 15mg:
MAL25106019ACZ

Roxavid Film Coated Tablets 20mg:
MAL25106018ACZ

Manufacturer

Inventia Healthcare Limited,
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Product Registration Holder

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