

VASIRIVA 10 (Rivaroxaban Film-coated Tablets 10mg)

Rivaroxaban (10mg film-coated tablets)

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1. What VASIRIVA 10 is used for

VASIRIVA 10 contains the active substance rivaroxaban and is used in adults to:

- prevent blood clots in the veins after a hip or knee replacement operation. Your doctor has prescribed this medicine for you because after an operation you are at an increased risk of getting blood clots

2. How VASIRIVA 10 works

VASIRIVA 10 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.

3. Before you use VASIRIVA 10

- When you must not use it

Do not take VASIRIVA 10

- 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 are breast-feeding

Do not take VASIRIVA 10 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 VASIRIVA 10.

Take special care with VASIRIVA 10,

- if you have an increased risk of bleeding, as could be the case in situation such as:
 - moderate or severe kidney disease, since your kidney function may affect the amount of medicine that works in your body
- if you are taking other medicine 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

- 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 are planned

If any of the above apply to you, tell your doctor before you take VASIRIVA 10. Your doctor will decide, if you should be treated with this medicine and if you

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should be kept under closer observation.

If you need to have an operation

- It is very important to take VASIRIVA 10 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 VASIRIVA 10 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

VASIRIVA 10 is not recommended for people under 18 years of age. There is not enough information on its use in children and adolescents.

Pregnancy and breast-feeding

Do not take VASIRIVA 10 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 VASIRIVA 10. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

VASIRIVA 10 contains lactose.

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

• 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 on 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)
 - anti-inflammatory and pain-relieving medicines (e.g., naproxen or acetylsalicylic acid)
 - dronedarone, a medicine to treat abnormal heartbeat
 - 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 VASIRIVA 10, because the effect of VASIRIVA 10 may be increased. Your doctor will decide, if you should be treated with this medicine and if you should be kept under close 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 VASIRIVA 10, because the effect of VASIRIVA 10 may be reduced.

Your doctor will decide, if you should be treated with VASIRIVA 10 and if you should be kept under closer observation.

4. How to use VASIRIVA 10

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

- How much to use

To prevent blood clots in the veins after a hip or knee replacement operation: The

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recommended dose is one tablet VASIRIVA 10mg once a day.

Swallow the tablet preferably with water. VASIRIVA 10 can be taken with or without food.

If you have difficulty swallowing the whole tablet, talk to your doctor about other ways to take VASIRIVA 10. 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 VASIRIVA 10 tablet through a stomach tube.

- 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.

To prevent blood clots in the veins after a hip or knee replacement operation: Take the first tablet 6 - 10 hours after your operation.

If you have had a major hip operation you will usually take the tablets for 5 weeks. If you have had a major knee operation you will usually take the tablets for 2 weeks.

- How long to use it

Keep taking VASIRIVA every day for as long as your doctor tells you. Do not stop taking VASIRIVA 10 without talking to your doctor first, because VASIRIVA 10 prevents the development of a serious

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

- If you forget to use it

If you have missed a dose, take it as soon as you remember. Take the next tablet on the following day and then carry on taking a tablet once a day as normal. Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

Contact your doctor immediately if you have taken too many VASIRIVA 10 tablets. Taking too much VASIRIVA 10 increased the risk of bleeding.

5. While you are using it

- Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking VASIRIVA 10.

- Things you must not do

- Do not stop taking your medicines without consulting your doctor.
- Do not use VASIRIVA 10 after the expiry date which is stated on the carton and blister.
- Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

Driving and using machines

VASIRIVA 10 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.

6. Side effects

Like all medicines, VASIRIVA 10 can cause side effects, although not everybody gets them.

Like other similar medicines to reduce the formation of blood clots, VASIRIVA 10 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 close observation or change the treatment.

Possible side effects which may be sign of severe skin reaction. Tell your doctor immediately if you experience skin reactions such as:

- spreading intense skin rash, blister 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

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abnormalities and systemic illness (DRESS syndrome).

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 of blood pressure.
- anaphylactic reactions, including anaphylactic shock) and uncommon angioedema and allergic oedema.

Overall list of possible side effects

Common

- 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
- 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

- 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

- 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)

Not known

- 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)

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)]

7.Storage and Disposal of VASIRIVA 10

- Storage

Store at temperature not exceeding 30°C.

- 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.

8. Product Description

- What it looks like

Orange, film coated, round shaped biconvex tablets, debossed with "R21" on one side and "H" on the other side.

- Ingredients

- Active ingredient(s)

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- Inactive ingredients

Tablet core: Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose (2910), sodium lauryl sulphate, magnesium stearate.

Tablet film coat: Hypromellose (2910), macrogol (E1521), titanium dioxide (E 171), iron oxide yellow (E 172), iron oxide red (E172).

- MAL number:

MALXXXXXXXXX

9. Manufacturer and Product Registration Holder

Manufacturer

Hetero Labs Limited
Unit-V, Block V and V-A,
TSIIC – Formulation SEZ,
S. Nos 439, 440, 441 & 458,
Pollepally Village, Jadcheerla
Mandal, Mahaboobnagar District,
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Product Registration Holder Camber Laboratories Sdn. Bhd.

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10. Date of revision

1st August 2024

11. Serial Number

NPRA (R2) 22/168