

VASIRIVA 2.5 (Rivaroxaban Film-coated Tablets 2.5mg)

Rivaroxaban (2.5mg film-coated tablets)

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1. What VASIRIVA 2.5 is used for

You have been given VASIRIVA 2.5 because: You have been diagnosed with a high risk of getting a blood clot due to a coronary artery disease and/or peripheral artery disease which causes symptoms.

VASIRIVA 2.5 reduces the risk in adults of getting blood clots [major atherothrombotic events (cardiovascular death, myocardial infarction and stroke)].

VASIRIVA 2.5 will not be given to you on its own. Your doctor will also tell you to take acetylsalicylic acid.

2. How VASIRIVA 2.5 works

VASIRIVA 2.5 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.

3. Before you use VASIRIVA 2.5

- When you must not use it

Do not take VASIRIVA 2.5

- if you are allergic to rivaroxaban or any of the other ingredients of this medicine (listed in section 8)
- 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 a bleeding or a blood clot in your brain (stroke)
- if you have coronary artery disease or peripheral artery disease and previously had a bleeding in your brain (stroke) or where there was a blockage of the small arteries providing blood to the brain's deep tissue (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 are breast-feeding

Do not take VASIRIVA 2.5 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 2.5. VASIRIVA 2.5 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.

Take special care with VASIRIVA 2.5

(1) if you have an increased risk of bleeding, as could be the case in situation 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 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
- you are older than 75 years
- you weigh 60 kg or less

(2) if you have a prosthetic heart valve

(3) 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.

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(4) Also take care if you have an active cancer – this may also mean you have an increased risk of bleeding. An active cancer means that in the last 6 months you:

- have been diagnosed with cancer
- had a relapse of cancer
- were being treated for cancer

If any of the above apply to you, tell your doctor before you take VASIRIVA 2.5. 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 VASIRIVA 2.5 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 2.5 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

VASIRIVA 2.5 is **not recommended for people under 18 years of age**.

There is not enough information on its use in children and adolescents.

- Taking other medicines

Other medicines and VASIRIVA 2.5

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, prasugrel and ticagrelor)
- 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 2.5, because the effect of VASIRIVA 2.5 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 2.5, because the effect of VASIRIVA 2.5 may be reduced. Your doctor will decide, if you should be treated with VASIRIVA 2.5 and if you should be kept under closer observation.

Pregnancy and breast-feeding

Do not take VASIRIVA 2.5 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 2.5. If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide how you should be treated.

VASIRIVA 2.5 contains lactose.

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

4. How to use VASIRIVA 2.5

- 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.

How much to take

The recommended dose is one 2.5mg tablet twice a day. Take VASIRIVA 2.5 around the same time every day (e.g., one tablet in the morning and one in the evening). This medicine can be taken with or without food.

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If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take VASIRIVA 2.5. 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 2.5 tablet through a stomach tube.

VASIRIVA 2.5 will not be given to you on its own.

Your doctor will tell you to take acetylsalicylic acid. Your doctor will tell you how much of these to take (usually between 75 to 100mg acetylsalicylic acid daily).

When to start VASIRIVA 2.5

- When to use it

Your doctor will tell you when to start treatment with VASIRIVA 2.5 if you have been diagnosed with coronary artery disease and/or peripheral artery disease.

Your doctor will decide how long you must continue treatment.

If you take more VASIRIVA 2.5 than you should

- If you use too much (overdose)

Contact your doctor immediately if you have taken too many VASIRIVA 2.5 tablets. Taking too much VASIRIVA 2.5 increased the risk of bleeding.

- If you forget to use it

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

If you stop taking VASIRIVA 2.5

- How long to use it

Take VASIRIVA 2.5 on a regular basis and for as long as your doctor keeps prescribing it.

Do not stop taking VASIRIVA 2.5 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.

5. 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 VASIRIVA 2.5.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

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

Do not give VASIRIVA 2.5 to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

Driving and using machines

VASIRIVA 2.5 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 2.5 can cause side effects, although not everybody gets them. Like other similar medicines to reduce the formation of blood clots, VASIRIVA

2.5 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 sign of severe skin reaction

- spreading intense skin rash, blister 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.
- a drug reaction that causes rash, fever, inflammation of internal organs, blood abnormalities and systemic illness (DRESS syndrome). The frequency of this side effect is very rare.

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

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difficulties; sudden drop of blood pressure.

The frequencies of severe allergic reactions 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).

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)

- bleeding in the kidney sometimes with presence of blood in urine leading to inability of the kidneys to work properly (anticoagulant-related nephropathy)

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)]

7.Storage and Disposal of VASIRIVA 2.5

- Storage

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

Store below 30 °C. Do not use this medicine after the expiry date which is stated on the label.

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

This medicine does not require any special storage conditions

- 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

White to off-white, film coated, round shaped biconvex tablets, debossed with "R20" on one side and "H" on the other side.

VASIRIVA 2.5 (Rivaroxaban Film-coated Tablets 2.5mg)

Rivaroxaban (2.5mg film-coated tablets)

- Ingredients

- Active ingredient(s)

Rivaroxaban 2.5 mg

- 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).

- 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, Jadcherla
Mandal, Mahaboobnagar District,
Telangana State, 509301 India

Product Registration Holder

Camber Laboratories Sdn. Bhd.
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Kuala Lumpur, Malaysia.

10. Date of revision

7th August 2024

11. Serial Number

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