Package leaflet: Information for the user

Rivaroxaban Vocate 10 mg, filmomhulde tabletten
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 VOCATE is and what it is used for
2. What you need to know before you take RIVAROXABAN VOCATE
3. How to take RIVAROXABAN VOCATE
4. Possible side effects
5. How to store RIVAROXABAN VOCATE
6. Contents of the pack and other information

1. What RIVAROXABAN VOCATE is and what it is used for

RIVAROXABAN VOCATE 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.
- 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.

RIVAROXABAN VOCATE 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 VOCATE

Do not take RIVAROXABAN VOCATE
- 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 breast-feeding

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

Warnings and precautions
Talk to your doctor or pharmacist before taking RIVAROXABAN VOCATE.

Take special care with RIVAROXABAN VOCATE
- if you have an increased risk of bleeding, as could be the case in situations 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 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 VOCATE")
  - 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) or tumours located in the stomach or bowels or genital tract or urinary tract
  - 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 RIVAROXABAN VOCATE. 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 VOCATE 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 VOCATE 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
RIVAROXABAN VOCATE 10 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 VOCATE
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)
    - 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 RIVAROXABAN VOCATE, because the effect of RIVAROXABAN VOCATE 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 RIVAROXABAN VOCATE, because the effect of RIVAROXABAN VOCATE may be reduced. Your doctor will decide, if you should be treated with RIVAROXABAN VOCATE and if you should be kept under closer observation.

Pregnancy and breast-feeding
Do not take RIVAROXABAN VOCATE 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 VOCATE. 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 VOCATE may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4 "Possible side effects"). You should not drive, ride a bicycle or use any tools or machines if you are affected by these symptoms.

RIVAROXABAN VOCATE 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".

3. How to take RIVAROXABAN VOCATE

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

- To prevent blood clots in the veins after a hip or knee replacement operation
  The recommended dose is one tablet RIVAROXABAN VOCATE 10 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

  After at least 6 months blood clot treatment, the recommended dose is either one 10 mg tablet once a day or one 20 mg tablet once a day. Your doctor has prescribed you RIVAROXABAN VOCATE 10 mg once a day.

Swallow the tablet preferably with water.
RIVAROXABAN VOCATE can be taken with or without food.

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

When to take RIVAROXABAN VOCATE
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.

If you take more RIVAROXABAN VOCATE than you should
Contact your doctor immediately if you have taken too many RIVAROXABAN VOCATE tablets. Taking too much RIVAROXABAN VOCATE increases the risk of bleeding.

If you forget to take RIVAROXABAN VOCATE
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 stop taking RIVAROXABAN VOCATE
Do not stop taking RIVAROXABAN VOCATE without talking to your doctor first, because RIVAROXABAN VOCATE prevents the development of a serious condition.

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 VOCATE can cause side effects, although not everybody gets them.

Like other similar medicines to reduce the formation of blood clots, RIVAROXABAN VOCATE 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. A serious medical emergency. Seek medical attention immediately!)
- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris

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; difficulty swallowing; hives and breathing difficulties; sudden drop in 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), 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 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 (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
- 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
- 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 a bleeding, which leads to pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after a 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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store RIVAROXABAN VOCATE

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 throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What RIVAROXABAN VOCATE contains
- The active substance is rivaroxaban. Each tablet contains 10 mg of rivaroxaban.
- The other ingredients are:

Tablet core: microcrystalline cellulose, croscarmellose sodium, lactose monohydrate,

hypromellose (2910), sodium laurilsulfate, magnesium stearate. See section 2 "RIVAROXABAN VOCATE contains lactose and sodium".

Tablet film coat: Opadry 04F540005 Pink consisting of hypromellose (2910), titanium dioxide (E 171), polyethylene glycol, iron oxide red (E 172).

What RIVAROXABAN VOCATE looks like and contents of the pack

RIVAROXABAN VOCATE 10 mg film-coated tablets are pink, round, biconvex tablets with the inscription "L2" on one side.
They come in blisters in cartons of 10 or 30 film-coated tablets.

Marketing Authorisation Holder
Vocate Pharmaceuticals SA
150 Gounari str., 166 74 Glyfada
Athens, Greece

Manufacturer
Neuraxpharm Pharmaceuticals, SL
Avda. Barcelona, 69
08970 Sant Joan Despí
Barcelona, Spain

This medicinal product is authorized in the Member States of the EEA under the following names:

The Netherlands: Rivaroxaban Vocate 10 mg, filmomhulde tabletten
Greece: RIVAROXABAN/VOCATE 10 mg film coated tablets

This leaflet was last revised in december 2023