

WARNING: (A) PREMATURE DISCONTINUATION OF VAROXO INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HAEMATOMA

A. Premature discontinuation of VAROXO increases the risk of thrombotic events:

Premature discontinuation of any oral anticoagulant, including VAROXO, increases the risk of thrombotic events. If anticoagulation with VAROXO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. Spinal/epidural haematoma:

Epidural or spinal hematomas have occurred in patients treated with VAROXO who are receiving neuraxial anaesthesia or undergoing spinal puncture. These haematomas may result in long-term or permanent paralysis.

Consider these risks when scheduling patients for spinal procedures.

Factors that can increase the risk of developing epidural or spinal haematomas in these patients include:

- Use of indwelling epidural catheters
- Concomitant use of other medicines that affect haemostasis, such as nonsteroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- History of traumatic or repeated epidural or spinal punctures
- History of spinal deformity or spinal surgery
- Optimal timing between the administration of VAROXO and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

SCHEDULING STATUS:

S4

VAROXO 10 (10 mg) film-coated tablets

VAROXO 10: Each film-coated tablet contains 10 mg rivaroxaban.

Contains sugar (lactose monohydrate): 21 mg

VAROXO 15 (15 mg) film-coated tablets

VAROXO 15: Each film-coated tablet contains 15 mg rivaroxaban.

Contains sugar (lactose monohydrate): 31,5 mg

VAROXO 20 (20 mg) film-coated tablets

VAROXO 20: Each film-coated tablet contains 20 mg rivaroxaban.

Contains sugar (lactose monohydrate): 42 mg

Read all of this leaflet carefully before you start taking VAROXO.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VAROXO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What VAROXO is and what it is used for
2. What you need to know before you take VAROXO
3. How to take VAROXO
4. Possible side effects
5. How to store VAROXO
6. Contents of the pack and other information

1. What VAROXO is and what it is used for

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

VAROXO 10 is used in adults to:

- prevent blood clots in the veins after major surgery in your lower limbs. Your doctor has prescribed this medicine for you because after an operation you are at an increased risk of getting blood clots.

VAROXO 15 and 20 are used in adults to:

- prevent blood clots in the 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 recurring in the blood vessels of your legs and/or lungs.

2. What you need to know before you take VAROXO

Do not take VAROXO:

- if you are hypersensitive (allergic) to rivaroxaban or any of the other ingredients of VAROXO (listed in section 6).
- if you have a tendency of 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, spine or eyes).
- if you are taking medicines to prevent blood clotting (e.g. warfarin 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 breastfeeding.
- if you have a disease called triple positive antiphospholipid syndrome (a disorder in which the immune system mistakenly attacks normal proteins in the blood resulting in increased risk of blood clots).
- if you have an inherited bleeding disorder

Warnings and precautions

Take special care with VAROXO:

- 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.
- 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).
- recent bleeding in your brain (intracranial or intracerebral bleeding).
- a recent operation on your brain, spinal column or eye.
- if you have a lung disease called bronchiectasis. Bronchiectasis is a disease in which there is a permanent enlargement of parts of the airways of the lung. Symptoms typically include a chronic cough with mucus production. Other symptoms include shortness of breath, coughing up blood, and chest pain.
- 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 you are women of childbearing potential only with contraception.

If any of the above applies to you, tell your doctor before you take VAROXO. Your doctor will decide, if you should be treated with VAROXO and if you should be kept under close observation.

If you need to have an operation:

- it is very important to take VAROXO 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 VAROXO 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

Do not give VAROXO to people under 18 years of age.

Other medicines and VAROXO

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking:

The following medicines that can enhance the effect of VAROXO and lead to increase in bleeding risk:

- some medicines for fungal infections (e.g. ketoconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin;
- ketoconazole tablets (used to treat Cushing's syndrome – a medical condition where your body produces an excess of cortisol);
- 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);

If any of the above applies to you, tell your doctor before taking VAROXO, because the effect of VAROXO 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:

- rifampicin (used to treat tuberculosis (TB))
- phenytoin, carbamazepine, phenobarbitone (used to treat epilepsy or fits) or St. John's Wort (a dietary supplement used to treat depression)
- anti-inflammatory and pain-relieving medicines (e.g. naproxen or acetylsalicylic acid); some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs)) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- some medicines for bacterial infections (e.g., clarithromycin, erythromycin)
- a medicine to treat abnormal heartbeat (e.g., dronedarone).

If any of the above applies to you, tell your doctor before taking VAROXO, because the effect of VAROXO may be reduced. Your doctor will decide, if you should be treated with VAROXO and if you should be kept under closer observation.

VAROXO with food and drink

VAROXO 10 can be taken with or without food.

VAROXO 15 and VAROXO 20 should be taken with food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking VAROXO.

Pregnancy

Do not take VAROXO if you are pregnant. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking VAROXO. If you become pregnant while you are taking VAROXO, tell your doctor immediately, who will decide how you should be treated.

Breastfeeding

Do not use VAROXO if you are breastfeeding.

Driving and using machines

VAROXO may cause dizziness or fainting. You should not drive or use machines if you are affected by these symptoms.

VAROXO contains lactose

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

3. How to use VAROXO

Do not share medicines prescribed for you with any other person.

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

VAROXO 10:

The usual dose is:

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

When to take VAROXO 10:

Take the first tablet 6 – 10 hours after your operation.

Then take a 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.

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.

VAROXO 15 and VAROXO 20:

The usual dose is:

- To prevent blood clots in brain (stroke) and other blood vessels in your body the recommended dose is one 20 mg tablet once a day. If you have kidney problems, the dose may be reduced to one 15 mg tablet 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 15 mg tablet twice a

day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one 20 mg tablet once a day. If you have kidney problems, your doctor may decide to reduce the dose for the treatment after 3 weeks to one 15 mg tablet once a day if the risk for bleeding is greater than the risk for having another blood clot.

Your doctor will tell you how long your treatment with VAROXO will last. Do not stop treatment early. If you have the impression that the effect of VAROXO is too strong or too weak, tell your doctor or pharmacist.

Use in children and adolescents

VAROXO should not be given to children or adolescents under 18 years.

If you take more VAROXO than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VAROXO:

VAROXO 10

If you are taking one 10 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.

VAROXO 15

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.

VAROXO 20

If you are taking one 20 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.

If you stop taking VAROXO:

Don't stop taking VAROXO without talking to your doctor first, because VAROXO treats and prevents serious conditions.

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

4. Possible side effects

VAROXO can have side effects.

Not all side effects reported for VAROXO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VAROXO, please consult your health care provider for advice.

VAROXO 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 how you should be treated.

Side effects which may be experienced frequently:

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness;
- headache, dizziness;
- fever;
- bleeding into the eye (including bleeding from the whites of the eyes);
- low blood pressure (symptoms may be feeling dizzy or fainting when standing up), bleeding into a cavity of the body (haematoma, bruising);
- nose bleeds and coughing up blood;
- bleeding in the stomach or bowel, bleeding from the rectum, stomach pains, bleeding in the gum;
- indigestion, nausea, constipation, diarrhoea, vomiting;
- blood tests may show an increase in some liver enzymes
- rash, itchy skin;
- bleeding from the skin or under the skin;
- pain in the limbs;
- bleeding from genitals (including passing blood in the urine and heavy menstrual bleeding);
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever, decreased general strength and energy (weakness, tiredness), swelling in the limbs;
- bleeding following an operation, oozing of blood from surgical wound;

Side effects which may be experienced less frequent:

- decrease in platelets (substances that help the blood to clot) in your blood;
- allergic reactions, including allergic skin reactions;
- bleeding into the brain or inside the skull, loss of consciousness caused by a fall in blood pressure;
- fast heartbeat;
- dry mouth;
- impaired function of the liver (may be seen in tests performed by your doctor) and jaundice (yellowing of skin and eyes)
- severe skin rash on the skin and in mucosal lining (like in the mouth) with severe blistering accompanied by fever;

- bleeding into a muscle,
- localised swelling, feeling unwell;
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets;
- false aneurysm (a collection of blood that forms between the two outer layers of an artery).

Side effects with unknown frequency:

- compartment syndrome (swelling of a limb) caused by bleeding into the tissue or muscle;
- impaired function of the kidneys (may be seen in tests performed by your doctor)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VAROXO.

5. How to store VAROXO

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Keep blister strips in the outer carton until required for use.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What **VAROXO** contains

The active substance is rivaroxaban.

VAROXO 10: Each film-coated tablet contains 10 mg rivaroxaban.

VAROXO 15: Each film-coated tablet contains 15 mg rivaroxaban.

VAROXO 20: Each film-coated tablet contains 20 mg rivaroxaban.

The other ingredients are:

Colloidal silicon dioxide, croscarmellose sodium, ferrosoferric oxide /black iron oxide (E172) (15 mg and 20 mg), iron oxide red (E172), lactose monohydrate, macrogol, magnesium stearate (vegetable source), microcrystalline cellulose hypromellose, sodium lauryl sulfate, titanium dioxide (E171), talc (10 mg).

What VAROXO looks like and contents of the pack

VAROXO tablets are available in three strengths.

VAROXO 10: Round, pink, biconvex film-coated tablets debossed with “L” on one side and “10” on the other side.

VAROXO 15: Round, brown, biconvex film-coated tablets debossed with ‘504’ on one side and plain on the other side.

VAROXO 20: Triangle shaped, brown, film-coated tablets debossed with ‘505’ on one side and plain on the other side.

VAROXO is packed in blisters made of plain aluminium lidding foil and transparent PVC / PVdC film containing 10 or 14 film-coated tablets.

Pack sizes:

10 mg: cartons containing 10, 30 or 100 tablets

15 mg: cartons containing 10, 30, 40, 42 or 100 tablets

20 mg: cartons containing 10, 28, 30, 40 or 100 tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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