

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

Rivoxa® 10 (10 mg film-coated tablets)

Rivoxa® 15 (15 mg film-coated tablets)

Rivoxa® 20 (20 mg film-coated tablets)

Rivaroxaban

Contains sugar (lactose monohydrate)

- Each Rivoxa 10 film-coated tablet contains 28,09 mg lactose (as monohydrate).
- Each Rivoxa 15 film-coated tablet contains 21,068 mg lactose (as monohydrate).
- Each Rivoxa 20 film-coated tablet contains 28,09 mg lactose (as monohydrate).

Read all of this leaflet carefully before you start taking Rivoxa

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Rivoxa 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 Rivoxa is and what it is used for
2. What you need to know before you take Rivoxa
3. How to take Rivoxa
4. Possible side effects
5. How to store Rivoxa
6. Contents of the pack and other information

1. What Rivoxa is and what it is used for

Rivaroxaban, contained in Rivoxa, is a type of medicine known as an anticoagulant, or blood thinner. It makes your blood flow through your veins more easily. This means your blood will be less likely to form a blood clot.

Rivoxa 10 mg is used in adults to:

- prevent blood clots in the veins after undergoing major orthopaedic (bone) surgery. After an operation you are at an increased risk of getting blood clots.

Rivoxa 15 and 20 mg is 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 (SPAF);
- treat blood clots in the veins of your legs (deep vein thrombosis (DVT)) and in the blood vessels of your lungs (pulmonary embolism (PE)), and to prevent blood clots from re-occurring in the blood vessels (DVT) of your legs and/or lungs.

2. What you need to know before you take Rivoxa

Do not take Rivoxa:

- if you are allergic to rivaroxaban or any of the other ingredients of Rivoxa (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 breastfeeding.

Warnings and precautions

Take special care with Rivoxa:

Talk to your doctor or pharmacist before taking Rivoxa:

- 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 or medicines which affect the process which causes bleeding to stop. See Other medicines and Rivoxa;
 - bleeding disorders (acquired or inherited);
 - 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 applies to you, tell your doctor before you take Rivoxa. 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:

- Tell your doctor if you are taking Rivoxa; it is very important to take Rivoxa 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 Rivoxa 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:

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

Other medicines and Rivoxa

Always tell your healthcare provider (doctor, nurse, pharmacist or other) if you are taking any other medicine. This includes all complementary or traditional medicines.

The use of Rivoxa with other medicines may cause undesirable interactions.

Before taking Rivoxa, tell your doctor if you are taking any of the following medicines, which may *increase* the effect of Rivoxa:

- some medicines for fungal infections (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, fluconazole), unless they are only applied to the skin;
- medicines for bacterial infections (some antibiotics like 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)),

Your doctor will decide if you should be treated with Rivoxa 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, she/he may also prescribe a preventative ulcer treatment.

Before taking Rivoxa, tell your doctor if you are taking any of the following, because the effect of Rivoxa may be *reduced* 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.

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

Rivoxa with food and drink

Rivoxa 10 mg can be taken with or without food. Swallow the tablet with water.

Rivoxa 15 mg and Rivoxa 20 mg must be taken **with food**. Swallow the tablet with water.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, nurse, pharmacist or other healthcare provider for advice.

Do not take Rivoxa if you are pregnant or breastfeeding.

If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking Rivoxa.

If you become pregnant while you are taking Rivoxa, tell your doctor immediately, who will decide how you should be treated.

Driving and using machines

Rivoxa may cause dizziness or fainting (see Possible side effects). You should not drive or use machines if you are affected by these symptoms.

Rivoxa contains lactose

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

3. How to take Rivoxa

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

Always take Rivoxa exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Rivoxa 10:

The usual dose is one Rivoxa 10 mg tablet once a day to prevent blood clots after a major operation.

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

Then take a tablet every day until your doctor tells you to stop.

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.

Take the tablet with water and with or without meals, until your doctor tells you to stop.

Try to take the tablet(s) at the same time every day to help you to remember it. Your doctor will decide how long you must continue your treatment.

Rivoxa 15 and 20:

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

The usual dose is one Rivoxa 20 mg tablet once a day. If your kidneys are not working properly, your doctor may decide to reduce your dose to one Rivoxa 15 mg tablet once a day.

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

The usual dose is one Rivoxa 15 mg tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one Rivoxa 20 mg tablet once a day.

Your doctor will tell you what dose to take and for how long you should keep on taking Rivoxa.

When to take Rivoxa 15 and 20 mg:

Take the tablet(s) every day with water and **with meals**, until your doctor tells you to stop.

Try to take the tablet(s) at the same time every day to help you to remember it. Your doctor will decide how long you must continue your treatment.

If you take more Rivoxa than you should:

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

Taking too much Rivoxa increases the risk of bleeding.

If you forget to take Rivoxa:

Do not take a double dose to make up for forgotten individual doses.

- If you have missed a Rivoxa 10 mg 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 are taking one Rivoxa 15 mg or one Rivoxa 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 are taking one Rivoxa 15 mg tablet **twice** a day and have missed a dose, take it as soon as you remember. Do not take more than two Rivoxa 15 mg tablets in a single day. If you forget to take a dose you can take two Rivoxa 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 Rivoxa 15 mg tablet twice a day.

If you stop taking Rivoxa:

Do not stop taking Rivoxa without talking to your doctor first, because Rivoxa 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

Rivoxa can have side effects.

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

If any of the following happens, stop taking Rivoxa and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing and breathing difficulties; sudden drop in blood pressure (angioedema, anaphylactic reactions, including anaphylactic shock)
- a medicine reaction that causes rash, fever, inflammation of internal organs, blood abnormalities and systemic illness (DRESS syndrome)
- a spreading, intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Rivoxa. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- long or excessive bleeding, which may potentially be life-threatening. Excessive bleeding may lead to a sudden drop in blood pressure (shock). In some cases these bleedings may not be obvious. Some signs of bleeding may be exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain (angina pectoris). Your doctor may decide to keep you under closer observation or change how you should be treated
- 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).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- headache
- dizziness
- bleeding into the eye (including bleeding from the whites of the eyes)
- bleeding into tissue or a cavity of the body (haematoma, bruising)
- bleeding in the stomach or bowel, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), bleeding in the gums, bleeding in the rectum
- bleeding following an operation
- nose bleeding, coughing up of blood.
- bleeding from the skin or under the skin
- low blood pressure
- stomach ache, indigestion, feeling sick or being sick (nausea and vomiting), constipation, diarrhoea
- blood tests may show an increase in some liver enzymes
- rash, itchy skin
- pain in the limbs
- impaired function of the kidneys (shown in laboratory test)
- fever
- decreased general strength and energy (weakness, tiredness)
- swelling in the limbs.

Less frequent side effects

- blood tests may show an increase in the number of platelets, in bilirubin, or some pancreatic enzymes
- bleeding into the brain or inside the skull

- fainting (including loss of consciousness).
- bleeding into a joint causing pain and swelling
- bleeding into a muscle
- faster heartbeat
- dry mouth
- cholestasis (decreased bile flow), hepatitis including hepatocellular injury (inflamed liver including liver injury)
- jaundice (yellowing of the skin and eyes)
- 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)
- kidney failure after a severe bleeding
- feeling unwell
- localised swelling
- oozing of blood or fluid from surgical wound
- collection of blood (haematoma) following complication in a cardiac procedure where a catheter is inserted to treat narrowed coronary arteries (pseudoaneurysm).

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the 6.04 Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Rivoxa.

5. How to store Rivoxa

Store all medicines out of reach of children.

Store at or below 25 °C. Keep blister strips in the original carton until use.

Do not store in a bathroom.

Do not use Rivoxa after the expiry date which is stated on the carton and on each blister strip.

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

The active substance is rivaroxaban.

Rivoxa 10, 15 and 20 film-coated tablets contain 10 mg, 15 mg and 20 mg rivaroxaban respectively.

The other ingredients are:

Tablet core:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulphate, colloidal anhydrous silica, magnesium stearate.

Film coating:

Hypromellose (E464), iron oxide red (E172), titanium dioxide (E171) and macrogol (E1521).

What Rivoxa looks like and contents of the pack:

Rivoxa 10 mg:

Light-red, round, biconvex, film-coated tablet, debossed with "C5" on one side and plain on the other side.

The tablets are packed in Alu hard tempered foil – clear film PVC/PVDC blister pack. The blister strips are packed in cartons containing 10, 15, 30 tablets.

Not all pack sizes may be marketed.

Rivoxa 15 mg:

Red, round, biconvex, film-coated tablet, debossed with “C4” on one side, plain on the other side.

The tablets are packed in Alu hard tempered foil – clear film PVC/PVDC blister pack. The blister strips are packed in cartons containing 28, 30 or 42 tablets.

Not all pack sizes may be marketed.

Rivoxa 20 mg:

Brown-red, round, biconvex, film-coated tablet, debossed with “C3” on one side and plain on the other side.

The tablets are packed in Alu hard tempered foil – clear film PVC/PVDC blister pack. The blister strips are packed in cartons containing 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer:

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RIVOX A 15 – 56/8.2/1009

RIVOX A 20 – 56/8.2/1010

Access to the corresponding Professional Information

For professional information, please refer to the SAHPRA Repository of Professional Information and Patient Information Leaflets: <https://www.sahpra.org.za/pi-pil-repository/>.

RIV/PIL/A