

CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RIVAROXABAN ADCO 10 (10 mg) film-coated tablets

Contains sugar (lactose monohydrate): 21 mg

RIVAROXABAN ADCO 15 (15 mg) film-coated tablets

Contains sugar (lactose monohydrate): 31,5 mg

RIVAROXABAN ADCO 20 (20 mg) film-coated tablets

Contains sugar (lactose monohydrate): 42 mg

Rivaroxaban

Read all of this leaflet carefully before you start taking RIVAROXABAN ADCO.

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

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

RIVAROXABAN ADCO 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.

RIVAROXABAN ADCO 10 is used in adults to:

- prevent blood clots in the veins after a 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.

RIVAROXABAN ADCO 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 RIVAROXABAN ADCO

Do not take RIVAROXABAN ADCO:

- if you are hypersensitive (allergic) to rivaroxaban or any of the other ingredients of RIVAROXABAN ADCO (see **What RIVAROXABAN ADCO contains**).
- 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 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 breast feeding.

Warnings and precautions

Take special care with RIVAROXABAN ADCO:

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

If you need to have an operation:

- it is very important to take RIVAROXABAN ADCO 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 ADCO 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 RIVAROXABAN ADCO to people under 18 years of age.

Other medicines and RIVAROXABAN ADCO:

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 RIVAROXABAN ADCO 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) as it may enhance the effect of;
- 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 RIVAROXABAN ADCO, because the effect of RIVAROXABAN ADCO 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)

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

RIVAROXABAN ADCO with food and drink

RIVAROXABAN ADCO 10 can be taken with or without food.

RIVAROXABAN ADCO 15 and RIVAROXABAN ADCO 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 RIVAROXABAN ADCO.

Pregnancy

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

Breastfeeding

Do not use RIVAROXABAN ADCO if you are breastfeeding.

Driving and using machines:

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

RIVAROXABAN ADCO contains lactose

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

3. How to use RIVAROXABAN ADCO

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

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

RIVAROXABAN ADCO 10:

The usual dose is:

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

When to take RIVAROXABAN ADCO 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.

RIVAROXABAN ADCO 15 and RIVAROXABAN ADCO 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 RIVAROXABAN ADCO will last. Do not stop treatment early. If you have the impression that the effect of RIVAROXABAN ADCO is too strong or too weak, tell your doctor or pharmacist.

Use in children and adolescents

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

If you take more RIVAROXABAN ADCO 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 RIVAROXABAN ADCO:

RIVAROXABAN ADCO 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.

RIVAROXABAN ADCO 15

If you are taking one RIVAROXABAN ADCO 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.

RIVAROXABAN ADCO 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.

4. Possible side effects

RIVAROXABAN ADCO can have side effects.

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

RIVAROXABAN ADCO 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;
- 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;
- 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);
- 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:

RIVAROXABAN ADCO 10

- 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 and jaundice;
- impaired function of the liver (may be seen in tests performed by your doctor)
- severe skin rash on the skin and in mucosal lining (like in the mouth) with severe blistering accompanied by fever;
- bleeding into a muscle, 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)
- localised swelling, fever, feeling unwell;
- blood tests may show an increase in some pancreatic or liver enzymes;
- false aneurysm (a collection of blood that forms between the two outer layers of an artery)

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 **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 RIVAROXABAN ADCO.

5. How to store RIVAROXABAN ADCO

- 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 **RIVAROXABAN ADCO** contains

The active substance is rivaroxaban.

RIVAROXABAN ADCO 10: Each film-coated tablet contains 10 mg rivaroxaban.

RIVAROXABAN ADCO 15: Each film-coated tablet contains 15 mg rivaroxaban.

RIVAROXABAN ADCO 20: Each film-coated tablet contains 20 mg rivaroxaban.

The other ingredients (excipients) are:

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

What **RIVAROXABAN ADCO** looks like and contents of the pack

RIVAROXABAN ADCO tablets are available in three strengths.

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

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

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

RIVAROXABAN ADCO is packed in plain aluminum lidding foil and transparent PVC / PVdC film containing 10 film-coated tablets.

Pack sizes:

10 mg: cartons containing 10, 30 or 100 tablets

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

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

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