Approved Patient Information Leaflet for Medicines for Human Use:

REZALTO 10 mg

SCHEDULING STATUS: S4

REZALTO 10 mg film-coated tablets

Rivaroxaban

Contains sugar: lactose monohydrate 95,6 mg/tablet

Read all of this leaflet carefully before you start taking REZALTO 10 mg

- 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.
- REZALTO 10 mg 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 REZALTO 10 mg is and what it is used for
2. What you need to know before you take REZALTO 10 mg
3. How to take REZALTO 10 mg
4. Possible side effects
5. How to store REZALTO 10 mg
6. Contents of the pack and other information

1. What REZALTO 10 mg is and what it is used for

REZALTO 10 mg 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.

REZALTO 10 mg contains the active substance rivaroxaban and is used in adults to prevent blood clots in the veins (deep vein thrombosis) in patients undergoing an operation of the lower limbs, because after an operation you are at an increased risk of getting blood clots.

2. What you need to know before you take REZALTO 10 mg

Do not take REZALTO 10 mg

- if you are hypersensitive (allergic) to rivaroxaban or any of the other ingredients of REZALTO 10 mg (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 have a disease called antiphospholipid syndrome (APS) as you are at an increased risk of recurrent arterial blood clots (thrombotic events),
- if you are pregnant or breast-feeding.

Do not take REZALTO 10 mg and tell your doctor if any of these apply to you.

Warnings and precautions

Take special care with REZALTO 10 mg:

- 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 REZALTO 10 mg)”
- 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.

- if you have a prosthetic heart valve.
- 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 REZALTO 10 mg. 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 REZALTO 10 mg 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 REZALTO 10 mg 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

REZALTO 10 mg is not recommended for people under 18 years of age. There is not enough information on its use in children and adolescents.

Other medicines and REZALTO 10 mg

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 REZALTO 10 mg, because the effect of REZALTO 10 mg 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, phenobarbitone),
- 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 REZALTO 10 mg, because the effect of REZALTO 10 mg may be reduced. Your doctor will decide, if you should be treated with REZALTO 10 mg and if you should be kept under closer observation.

Pregnancy and 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 this medicine.

Do not take REZALTO 10 mg 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 REZALTO 10 mg. 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

REZALTO 10 mg may cause dizziness or fainting. You should not drive or use machines if you are affected by these symptoms.

REZALTO 10 mg contains lactose

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

3. How to take REZALTO 10 mg

Do not share medicines prescribed for you with any other person.
Always take REZALTO 10 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

- One tablet of REZALTO 10 mg once a day.

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

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take REZALTO 10 mg. 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 REZALTO 10 mg tablet through a stomach tube.

Your doctor will tell you how long your treatment with REZALTO 10 mg will last. If you have the impression that the effect of REZALTO 10 mg is too strong or too weak, tell your doctor or pharmacist.

When to take REZALTO 10 mg

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 REZALTO 10 mg than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Don’t forget to take your container with you. This could indicate how many tablets have been taken. Taking too much REZALTO 10 mg increases the risk of bleeding.

If you forget to take REZALTO 10 mg

Take it when you remember and carry on as before unless it is time for the next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking REZALTO 10 mg

Do not stop taking REZALTO 10 mg without talking to your doctor first, because REZALTO 10 mg 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

REZALTO 10 mg can have side effects.

Not all side effects reported for REZALTO 10 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking REZALTO 10 mg, please consult your health care provider for advice.

REZALTO 10 mg 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 closer observation or change how you should be treated.

Possible side effects which may be a sign of severe skin reaction

Tell your doctor immediately if you experience skin reactions such as:

- Less frequent: spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens- Johnson syndrome/toxic epidermal necrolysis).
- Less frequent: a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome).

Possible side effects which may be a sign of a severe allergic reaction

Tell your doctor immediately if you experience any of the following side effects:

- Less frequent: swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties; sudden drop in blood pressure.

These are very serious side effects. If you have them, you may have had a serious reaction to REZALTO 10 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- 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 bleeds, 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 pain, 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.

Less frequent side effects

- 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,
- bleeding into a muscle,
- cholestasis (decreased bile flow), hepatitis including hepatocellular injury (inflamed liver including 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).

Frequency unknown:

- 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.

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 or nurse. 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 REZALTO 10 mg.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store REZALTO 10 mg

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package.
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Store all medicines out of reach and sight of children.

6. Contents of the pack and other information

What REZALTO 10 mg contains

- The active substance is rivaroxaban. Each tablet contains 10 mg of rivaroxaban.
- The other ingredients are:
    - Tablet core: cellulose microcrystalline, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, purified water, sodium laurilsulfate,
    - Film-coating: hypromellose 2910 (E464), titanium dioxide (E 171), macrogol 3350 (E1521), iron oxide red (E 172).

What REZALTO 10 mg looks like and contents of the pack

REZALTO 10 mg tablets are pink, round, biconvex film-coated tablets, engraved with “10”

Austell Pharmaceuticals (Pty) Ltd, 53/8.2/0194, Rezalto 10 mg film-coated tablets on one side, plain on the other.

The tablets are packed in PVC/Aluminium blisters in cartons of 10 or 30 tablets.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information

Access to the corresponding Afrikaans Patient Information Leaflet and latest Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

Austell Pharmaceuticals (Pty) Ltd

Austell Pharmaceuticals (Pty) Ltd, 53/8.2/0194, Rezalto 10 mg film-coated tablets

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