SCHEDULING STATUS

S4

REXARAV 10 mg Film-coated tablets

Rivaroxaban

Contains sugar: lactose monohydrate 20,250 mg

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

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

REXARAV 10 mg contains the active substance rivaroxaban. Rivaroxaban belongs to a group of medicines called antithrombotic medicines. It works by inhibiting blood clotting Factor Xa.

REXARAV 10 mg is used to prevent blood clots in your veins after a major operation on your legs. For example, this could be an operation on your hip or knee. Your doctor has prescribed **REXARAV 10 mg** for you because after an operation you are at an increased risk of getting blood clots.

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

Do not take REXARAV 10 mg:

- if you are hypersensitive (allergic) to rivaroxaban or any of the other ingredients of **REXARAV 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 are pregnant or breastfeeding.
- if you have been diagnosed with persistent triple positive antiphospholipid syndrome (APS).

Warnings and precautions

Tell your doctor or healthcare professional before taking REXARAV 10 mg:

Take special care with **REXARAV 10 mg** if:

- you have moderate or severe kidney disease
- you have an increased risk of bleeding such as:
  - bleeding disorders
  - very high blood pressure, not controlled by medical treatment
  - active ulcer or a recent ulcer of your stomach or bowel
  - a problem with the blood vessels in the back of your eyes (retinopathy)
  - recent bleeding in your brain (intracranial or intracerebral bleeding)
  - problems with your blood vessels in your brain or spinal column
  - a recent operation on your brain, spinal column or eye
  - a lung disease where your bronchi are widened and filled with pus (bronchiectasis), or
  - previous bleeding from your lung.
- if you have an artificial 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 need to have an operation:

- it is very important to take **REXARAV 10 mg** before and after the operation exactly at the times you have been told by your doctor. Inform your doctor that you are taking **REXARAV 10 mg**.

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 **REXARAV 10 mg** 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

REXARAV 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 REXARAV 10 mg

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

Especially tell your doctor if you are taking:

- some medicines for fungal infections (e.g. ketoconazole, itraconazole, voriconazole, posaconazole).
- some anti-retroviral medicines for HIV/AIDS (e.g. ritonavir).
- other medicines to reduce blood clotting (e.g. enoxaparin or clopidogrel or Vitamin K antagonists such as warfarin).
- anti-inflammatory and pain-relieving medicines (e.g. naproxen or acetylsalicylic acid).

Tell your doctor before taking **REXARAV 10 mg**, because its effect may be increased. Your doctor will decide if you should be treated with **REXARAV 10 mg** and if you should be kept under closer observation.

If your doctor thinks that you are at an increased risk to develop an ulcer of your stomach or bowel, he/she may also use a preventative ulcer treatment.

Also tell your doctor if you are taking:

- some medicines for treatment of epilepsy (phenytoin, carbamazepine, phenobarbital).
- St John's Wort, a herbal medicine used for depression.
- rifampicin, an antibiotic.

Tell your doctor before taking **REXARAV 10 mg**, because its effect may be reduced. Your doctor will decide if you should be treated with **REXARAV 10 mg** and if you should be kept under closer observation.

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, pharmacist or other health care provider for advice before you take **REXARAV 10 mg**.

If you are pregnant or breastfeeding do not take **REXARAV 10 mg**. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking **REXARAV 10 mg**. If you become pregnant while you are taking **REXARAV 10 mg**, immediately tell your doctor, who will decide how you should be treated.

Driving and using machines

REXARAV 10 mg may cause side effects such as dizziness or fainting (see "Possible side effects"). You should not drive or use machines if you are affected by these symptoms.

REXARAV 10 mg contains lactose

REXARAV 10 mg contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by

your doctor that you have an intolerance to some sugars, contact your doctor before taking **REXARAV 10 mg**.

3. How to take REXARAV 10 mg

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

Always take **REXARAV 10 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How much to take:

The usual dose is one **REXARAV 10 mg** tablet once a day.

Swallow the tablet preferably with water.

REXARAV 10 mg tablet can be taken with or without food.

When to take REXARAV 10 mg:

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.

Children and adolescents up to 18 years of age:

Don’t give **REXARAV 10 mg** tablets to people under 18 years of age. There is not enough information on its use in children and adolescents.

If you take more REXARAV 10 mg than you should

Taking too much **REXARAV 10 mg** increases the risk of bleeding.

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

If you forget to take REXARAV 10 mg:

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 REXARAV 10 mg:

Don't stop taking **REXARAV 10 mg** without talking to your doctor first, because **REXARAV 10 mg** treats and prevents serious conditions.

If you have any further questions on the use of **REXARAV 10 mg**, ask your doctor or pharmacist.

4. Possible side effects

REXARAV 10 mg can have side effects.

Not all side effects reported for **REXARAV 10 mg** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **REXARAV 10 mg**, please consult your health care provider for advice.

If any of the following happens, stop taking **REXARAV 10 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to **REXARAV 10 mg**. 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,
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained

swelling, breathlessness, chest pain (angina pectoris). These may be signs of bleeding.

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

Tell your doctor if you notice any of the following:

Frequent:

- 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),
- bleeding following an operation,
- swelling in the limbs,
- pain in the limbs,
- fever,
- reduction in red blood cells which can makethe skin pale and cause weakness or breathlessness,
- stomach ache, indigestion, feeling or being sick, constipation,
- decreased general strength and energy (weakness, tiredness), headache, dizziness,
- blood tests may show an increase in some liver enzymes,
- impaired function of the kidneys,
- bleeding from the skin or under the skin,
- coughing up blood.

Less frequent

- bleeding into the brain or inside the skull,

- bleeding into a joint causing pain and sweeting,
- oozing of blood or fluid from surgical wound,
- feeling unwell,
- dry mouth, allergic reactions, including allergic skin reactions, rash, itchy skin,
- hives,
- impaired function of the liver,
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets,
- raised heartbeat,
- fainting,
- bleeding into a muscle,
- collection of blood (haematoma) following complication in a cardiac procedure where a catheter is inserted to treat narrowed coronary arteries (pseudoaneurysm),
- localised swelling\yellowing of the skin and eye (jaundice).

Frequency unknown:

- 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.

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, pharmacist or nurse. You can also

report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of REXARAV.

5. How to store REXARAV 10 mg

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the blister in the carton until required for use.
- Do not use after the expiry date stated on the carton or label.

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 REXARAV 10 mg contains

- The active substance is rivaroxaban.

Each film-coated tablet contains rivaroxaban 10 mg.

Contains sugar: lactose monohydrate 20,250 mg per tablet.

- The other ingredients are:

Tablet core: cellulose microcrystalline, croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, sodium lauryl sulphate.

Film-coat: iron oxide red (E 172), macrogol, polyvinyl alcohol, talc, titanium dioxide (E 171).

What REXARAV 10 mg looks like and contents of the pack

REXARAV 10 mg is a light pink to pink coloured, film-coated, round, biconvex,

beveled edge tablet, debossed with RX on one side of the tablet and 2 on the other side. Dimensions: Diameter 5,4 mm ± 0,5 mm.

REXARAV 10 mg film-coated tablets are packed in blister strips (clear, transparent PVC coated with PVdC on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side. Blister strips contain 5 or 10 tablets per blister. Pack sizes: 5 tablets, 10 tablets, 30 tablets or 100 tablets.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

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Access to the corresponding Professional Information

To be confirmed.