SCHEDULING STATUS

S4

REXARAV 15 mg Film-coated tablets

REXARAV 20 mg Film-coated tablets

Rivaroxaban

Contains sugar: lactose monohydrate 30,375 mg and 40,500 mg respectively

Read all of this leaflet carefully before you take REXARAV

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

1. What REXARAV is and what it is used for

REXARAV contains the active substance rivaroxaban. Rivaroxaban belongs to a group of medicines called antithrombotic medicines. It works by blocking a blood clotting factor (Factor Xa) and thus reduces the tendency of the blood to clot.

REXARAV are used 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 to prevent blood clots from re-occurring in the veins of your legs and/or lungs (pulmonary embolism)
- treat blood clots in the blood vessels of your lungs (pulmonary embolism) and to prevent blood clots re-occurring in the blood vessels of your lungs and/or legs (deep vein thrombosis).

2. What you need to know before you take REXARAV

Do not take REXARAV:

- if you are hypersensitive (allergic) to rivaroxaban or any of the other ingredients of REXARAV (listed in section 6).
- if you have an inherited bleeding disorder
- if you have a liver disease which leads to an increased risk of bleeding
- if you are pregnant or breastfeeding.

Warnings and precautions

Tell your doctor or healthcare professional before taking REXARAV:

Take special care with REXARAV:

- if you have moderate or severe kidney disease
- if 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 have been diagnosed with persistent triple positive antiphospholipid syndrome (APS).

If you need to have an operation:

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

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 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 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

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, because its effect may be increased. Your doctor will decide if you should be treated with REXARAV 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, because its effect may be reduced. Your doctor will decide if you should be treated with REXARAV 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.

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

Driving and using machines

REXARAV 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 contains lactose

REXARAV 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.

3. How to take REXARAV

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

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

How much to take:

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

  The usual dose is one REXARAV 20 mg tablet once a day.

  If your kidneys are not working properly, the dose may be reduced to one REXARAV 15 mg tablet once a day.
- To treat blood clots in the veins of your legs and for preventing blood clots from re-occurring: The usual dose is one REXARAV 15 mg tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one REXARAV 20 mg tablet once a day.
- To treat blood clots in the blood vessels of your lungs and for preventing blood clots from re-occurring: The usual dose is one REXARAV 15 mg tablet twice a day for the first 3 weeks. For treatment after 3 weeks the usual dose is one REXARAV 20 mg tablet once a day.

Swallow the tablet preferably with water.

REXARAV tablets have to be taken with food.

When to take REXARAV:

Take the tablet(s) every day 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 treatment for.

If you take more REXARAV than you should

Taking too much REXARAV 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

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

If you stop taking REXARAV

Don't stop taking REXARAV without talking to your doctor first, because [PRODUT NAME] treats and prevents serious conditions.

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

4. Possible side effects

REXARAV can have side effects.

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

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

If any of the following happens, stop taking REXARAV 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. 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 make the 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

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 contains

- The active substance is rivaroxaban.

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

Contains sugar: lactose monohydrate 30,375 mg per tablet.

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

Contains sugar: lactose monohydrate 40,500 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 (only in 15 mg tablet), polyethylene glycol (only in 20 mg tablets), polyvinyl alcohol, talc, titanium dioxide (E 171).

What REXARAV looks like and contents of the pack

REXARAV 15 mg: A pink to brick red coloured, film-coated, round, biconvex, beveled edge tablet, debossed with RX on one side of the tablet and 3 on the other side. Diameter: Approximately 6,4 mm ± 0,5 mm

REXARAV 20 mg: A light pink to pink coloured, film-coated, round, biconvex, bevelled edge tablet, debossed with RX on one side of the tablet and 4 on the other side. Diameter: Approximately 7,0 mm ± 0,5 mm

REXARAV 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. Pack sizes: 14 tablets, 28 tablets, 42 tablets, 98 tablets or 100 tablets**.**

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To be confirmed.