PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RUBAROX 10; 15 & 20

Rivaroxaban 10 mg; 15 mg or 20 mg

Contains sugar: lactose monohydrate 27,90 mg, 25,40 mg and 22,90 mg respectively.

Read all of this leaflet carefully before you start taking RUBAROX

- 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.
- ***RUBAROX*** 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 RUBAROX is and what it is used for

The active substance is rivaroxaban. **RUBAROX** belong to a group of medicines called antithrombotic medicines. It works by blocking a blood clotting factor 25 (Factor Xa) and thus reduces the tendency of the blood to clot.

RUBAROX 15 and 20 mg tablets 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 from re-occurring in the blood vessels of your lungs and/or legs (deep vein thrombosis).

2. What you need to know before you take RUBAROX

Do not take RUBAROX and tell your doctor if any of the following apply to you:

- if you are allergic (hypersensitive) lo rivaroxaban or any of the other ingredients of **RUBAROX**
- if you have an inherited bleeding disorder
- if you have a liver disease which leads to an increased risk of bleeding
- if you have been diagnosed with persistent triple positive antiphospholipid syndrome (APS)
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with **RUBAROX**:

- if you have moderate or severe kidney disease
- if you have moderate liver disease
- 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).
- 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.

Tell your doctor before you take **RUBAROX** if any of these apply to you. Your doctor may decide if you should be treated with **RUBAROX** or if you should be kept under closer observation.

If you need to have an operation:

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

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 **RUBAROX** 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

RUBAROX 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 RUBAROX

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. ketoconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin
- some **antiretroviral 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 and acenocoumarol)
- **anti-inflammatory and pain relieving medicines** (e.g. naproxen or acetylsalicylic acid).

Tell your doctor before taking **RUBAROX** because its effect may be increased. Your doctor will decide if you should be treated with **RUBAROX** 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.

If you are taking:

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

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

RUBAROX with food, drink and alcohol

RUBAROX must 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 **RUBAROX**.

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

There is no information on fertility with **RUBAROX**

Driving and using machines

RUBAROX 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.

Important information about some of the ingredients of RUBAROX:

Lactose intolerance: **RUBAROX** contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **RUBAROX.**

3. How to take RUBAROX

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

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

How much to take:

- To prevent blood clots in the veins after a hip or knee replacement operation

  The recommended dose is one tablet **RUBAROX 10** once a day.

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

  The usual dose is one **RUBAROX 20** tablet once a day.

  If your kidneys are not working properly, the dose may be reduced to one **RUBAROX 15** 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 **RUBAROX 15** tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one **RUBAROX 20** 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 **RUBAROX 15** tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one **RUBAROX 20** tablet once a day.

Swallow the tablet preferably with water.

RUBAROX must be taken with food.

When to take RUBAROX:

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 RUBAROX than you should:

Contact your doctor immediately if you have taken too many **RUBAROX** tablets. Taking too much **RUBAROX** 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 RUBAROX:

- If you are taking one **RUBAROX** 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 **RUBAROX 10** or one **RUBAROX 15** tablet twice a day and have missed a dose, take it as soon as you remember. Do not take more than two **RUBAROX 10** or **RUBAROX 15** tablets in a single day. If you forget to take a dose you can take two **RUBAROX 10** or **RUBAROX 15** tablets at the same time to get a total of two tablets (20 mg or 30 mg respectively) on one day. On the following day you should carry on taking one **RUBAROX 10** or **RUBAROX 15** tablet twice a day.

If you stop taking RUBAROX:

Don’t stop taking **RUBAROX** without talking to your doctor first, because **RUBAROX** treats and prevents serious conditions.

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

4. Possible side effects

RUBAROX can have side effects.

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

RUBAROX may cause bleedings which may potentially be life threatening. Excessive bleeding may lead to sudden drop in blood pressure (shock). In some cases, these bleedings may not be obvious.

If any of the following happens, stop taking **RUBAROX** and tell your doctor immediately or go to the casualty department at your nearest hospital. 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 (angina pectoris). These may be signs of bleeding.

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

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

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

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

Your doctor may decide to keep you under closer observation or change how you should be treated.

It has been reported for **RUBAROX** that the following side effects can occur:

Frequent side effects:

- 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, diarrhoea
- low blood pressure
- decreased general strength and energy (weakness, tiredness), headache, dizziness
- rash, itchy skin
- 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 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)
- oozing of blood or fluid from surgical wound
- feeling unwell
- dry mouth

- allergic reactions, including allergic skin reactions
- 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 in your leg artery (pseudoaneurysm)
- localised swelling
- cholestasis (decreased bile flow), hepatitis incl. hepatocellular injury (inflamed liver incl. liver injury)
- yellowing of the skin and eye (jaundice).

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 any of these side effects continue or become bothersome, consult your health care provider.

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 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 **RUBAROX**.

5. How to store RUBAROX

Store all medicines out of reach of children.

Store at or below 25°C.

Store in the original package until use

6. Contents of the pack and other information

The active substance is rivaroxaban. Each tablet **RUBAROX 10** contains 10 mg*;* **RUBAROX 15** contains 15 mg and **RUBAROX 20** contains 20 mg of rivaroxaban.

Contains sugar (lactose monohydrate)

The other ingredients are:

Tablet core: cellulose microcrystalline, croscarmellose sodium, Hypromellose, magnesium stearate, sodium lauryl sulphate.

Film-coat: Hypromellose, titanium dioxide E171, macrogol, talc (20 mg), Iron oxide red (20 mg) or FD&C Blue #2 (10 mg)

What RUBAROX looks like and contents of the pack

10 mg film-coated tablet: Blue, biconvex, round, film coated tablets debossed "10" on one side, plain on other side.

15 mg film-coated tablet: White, biconvex, round, film coated tablets debossed "15" on one side, plain on other side.

20 mg film-coated tablet: Deep red, biconvex, round, film coated tablets debossed “20” on one side, plain on other side.

PVC/PVdC-peel push blister pack

Pack sizes of 10, 28, 30, 56, 60, 90 film-coated tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd

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