PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

RIVAR 15, (FILM COATED TABLETS)

RIVAR 20, (FILM COATED TABLETS)

Read all of this leaflet carefully before you start taking RIVAR

- 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.
- **RIVAR** 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

1. WHAT RIVAR IS AND WHAT IT IS USED FOR:

- **RIVAR** belong to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (Factor Xa) and thus reduces the tendency of the blood to clot.
- **RIVAR** prevent blood clots in the brain (stroke) and other blood vessel in your body if you have a form of irregular heart rhythm called non-valvular atrial fibrillation.
- **RIVAR treat blood clots** in the veins of your legs (deep vein thrombosis) and to **prevent blood clots** form re-occurring in the veins of your legs and/or lungs (pulmonary embolism).

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

Do not take RIVAR

- If you are allergic (hypersensitive) to RIVAR oxaban or to any ingredients of **RIVAR**
- If you have a bleeding disorder that you have inherited or 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 breastfeeding

RIVAR should not be used in children and adolescents**,** under 18 years of age.

Warnings and precautions

RIVAR should not be used in combination with certain other medicines which reduce blood clotting such as prasugrel or ticagrelor other than acetylsalicylic acid and clopidogrel/ticlopidine.

Take Special Care with **RIVAR:**

- If you suffer from moderate or severe kidney disease
- If you suffer from moderate liver 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, 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 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 **RIVAR** 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 **RIVAR** 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.

Other medicines and RIVAR

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are taking:

- some medicine for fungal infections (e.g. ketoconazole, itraconazole, voriconazole), unless they are only applied to the skin
- 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)
- some medicine for treatment of epilepsy (phenytoin, carbamazepine, phenobarbitone)
- St John's Wort, a herbal product used for depression

- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- rifampicin**,** an antibiotic
- dronedarone, a medicine to treat abnormal heartbeat

RIVAR with food and drink and alcohol

RIVAR must be taken with food.

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 **RIVAR** 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 **RIVAR.**

Driving and using machines

RIVAR may cause dizziness or fainting (see section 4, ”Possible side effects”). You should not drive or use machines if you are affected by these symptoms.

It is not always possible to predict to what extent **RIVAR** may interfere with the daily activities until they are aware of the measure to which **RIVAR** affects them.

RIVAR contains:

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

3. HOW TO TAKE RIVAR

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

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

You must take **RIVAR** together with a meal.

How much to take

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

The recommended dose is one tablet **RIVAR** 20 mg once a day.

If you have kidney problems, the dose may be reduced to one tablet **RIVAR** 15 mg 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 tablet **RIVAR** 15 mg twice a day for the first 3 weeks.

For treatment after 3 weeks, the recommended dose is one tablet **RIVAR** 20 mg once a day.

Your doctor will adjust your dose depending on your condition and response to treatment.

When to take RIVAR

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.

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

If your heartbeat needs to be restored to normal by a procedure called cardioversion, take **RIVAR** at the times your doctor tells you.

If you take more RIVAR than you should

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

Taking too much **RIVAR** increases the risk of bleeding.

If you forget to take RIVAR

Do not take a double dose to make up for forgotten individual doses.

- If you are taking one 20 mg tablet or one 15 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. Take the next tablet on the following day and then carry on taking one tablet once a day.
- If you are taking one 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.

If you stop taking RIVAR

Do not stop taking **RIVAR** without talking to your doctor first, because **RIVAR** treats and prevents serious conditions.

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

4. POSSIBLE SIDE EFFECTS

RIVAR can have side-effects.

*Not all side effects reported for **RIVAR** are included in this leaflet. Should your health worsen or if you experience any untoward effects while taking **RIVAR,** please consult your doctor, pharmacist or other health care professional for advice.*

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

Less frequent:

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties (angioedema); sudden drop in blood pressure.
- anaphylactic reactions, including anaphylactic shock
- allergic oedema
- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris, which may be signs of bleeding.
- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis).
- a medicine reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to **RIVAR .** 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), nosebleed, 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-ache, 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 incl. hepatocellular injury (inflamed liver incl. 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 not known:
- 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 "**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 **RIVAR**

5. HOW TO STORE RIVAR

KEEP OUT OF REACH OF CHILDREN

Any unused medicine or waste material should be returned to the pharmacy for destruction. Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

Store at or below 30 °C. Keep well closed. Protect from moisture and light.

Do not remove blister card from the carton until required for use.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RIVAR contains:

The active substance is RIVAR oxaban

Excipients:

RIVAR 15 – Lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate, opadry brown, titanium dioxide, macrogol / peg, iron oxide red, ferrosoferric oxide (NF) black.

RIVAR 20 – Lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate, opadry

brown, titanium dioxide, macrogol / peg, iron oxide red, ferrosoferric oxide (NF) black.

What RIVAR looks like and contents of the pack

RIVAR 15 round brown, biconvex film coated tablets, debossed with “504” on one side and plain on the other side.

RIVAR 20 triangle shaped, brown, film coated tablets, debossed with “505” on one side and plain on the other side.

RIVAR (Rivaroxaban) film-coated tablets are available as follows: A carton containing aluminium foil and transparent PVC/PVDC blister strips containing 10 tablets each.

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

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Johannesburg

2091

South Africa

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New

Registration number

RIVAR 15 mg: 55/8.2/0312

RIVAR 20 mg: 55/8.2/0313

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **RIVAR .**