Approved Patient Information Leaflet for Medicines for Human Use:

Rivaroxaban 15 mg Shanur and Rivaroxaban 20 mg Shanur

SCHEDULING STATUS: S4

RIVAROXABAN 15 mg SHANUR film-coated tablets

Contains sugar: lactose monohydrate 16,32 mg/tablet

RIVAROXABAN 20 mg SHANUR film-coated tablets

Contains sugar: lactose monohydrate 21,76 mg/tablet

Rivaroxaban

Read all of this leaflet carefully before you start taking RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR

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

1. WHAT RIVAROXABAN SHANUR is and what it is used for

RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR belong to a group of medicines called antithrombotic medicines. They work by decreasing the ability of your blood to form clots.

RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR are used to:

- prevent blood clots in the brain (stroke) and the other blood vessels in your body if you have a form of irregular heartbeat 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 in your 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 in your legs (deep vein thrombosis).

2. What you need to know before you take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

Do not take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

- if you are hypersensitive (allergic) to rivaroxaban or any of the other ingredients of RIVAROXABAN SHANUR (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.

Warnings and precautions

Talk to your doctor or pharmacist before taking RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR.

Take special care with RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR.

- if you have an increased risk of bleeding, as could be the case in situations such as:
    - 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 RIVAROXABAN SHANUR”)
    - 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 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 any of the above apply to you, tell your doctor before you take RIVAROXABAN SHANUR. 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 RIVAROXABAN SHANUR 15 mg or 20 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 ~~[PRODUCT NAME]~~ RIVAROXABAN SHANUR 15 mg or 20 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

RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR, because the effect of taking RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR, because the effect of RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR may be reduced. Your doctor will decide, if you should be treated with RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR. 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

RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR may cause dizziness or fainting. You should not drive or use machines if you are affected by these symptoms.

RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

Do not share medicines prescribed for you with any other person.
Always take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You must take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR together with a meal.
Swallow the tablet(s) preferably with water.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR. The tablet may be crushed and

mixed with water or apple puree immediately before you take it. This mixture should be immediately followed by food.

If necessary, your doctor may also give you the crushed RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR tablet through a stomach tube.

How much to take

- Your doctor will inform you regarding the dose you must take as well as the time at which to take the dose.
- To prevent blood clots in brain (stroke) and other blood vessels in your body the recommended dose is one tablet RIVAROXABAN 20 mg SHANUR once a day.
  If you have kidney problems, the dose may be reduced to one tablet RIVAROXABAN 15 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one tablet RIVAROXABAN 20 mg SHANUR once a day.

After at least 6 months blood clot treatment your doctor may decide to continue treatment with either one 10 mg tablet once a day or one 20 mg tablet once a day.

If you have kidney problems and take one tablet RIVAROXABAN 20 mg SHANUR once a day, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet RIVAROXABAN 15 mg SHANUR once a day if the risk for bleeding is greater than the risk for having another blood clot.

When to take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

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

RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR at the time your doctor tells you.

If you take more RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR than you should

In the event of 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.

If you forget to take RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

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 take more RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR than you should

Contact your doctor immediately if you have taken too many RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR tablets. Taking too much RIVAROXABAN SHANUR increases the risk of bleeding.

If you stop taking more RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

Do not stop taking RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR without talking to your doctor first, because RIVAROXABAN SHANUR 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

RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR can have side effects.

Not all side effects reported for RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIVAROXABAN 15 mg SHANUR and RIVAROXABAN 20 mg SHANUR, please consult your health care provider for advice.

RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR. 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 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 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 "**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 RIVAROXABAN SHANUR.

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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR

- 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR contains

- The active substance is rivaroxaban. Each tablet contains 15 mg or 20 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 RIVAROXABAN 15 mg SHANUR or RIVAROXABAN 20 mg SHANUR looks like and contents of the pack

RIVAROXABAN 15 mg SHANUR: Red, round, biconvex film-coated tablets, engraved with “15” on one side, plain on the other.

RIVAROXABAN 20 mg SHANUR: Brown - red round biconvex film coated tablets, engraved with “20” on one side, plain on the other.

The 15 mg tablets are packed in PVC/Aluminium blisters in cartons of 10, 30 or 42 tablets.

The 20 mg tablets are packed in PVC/Aluminium blisters in cartons of 10, 30 or 42 tablets.

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

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RIVAROXABAN 15 mg SHANUR: 53/8.2/0201

RIVAROXABAN 20 mg SHANUR: 53/8.2/0202

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

https://shanur.co.za/product-info/

Shanur Healthcare (Pty) Ltd

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