PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Rothrom® 10 (film-coated tablets)

Rothrom® 15 (film-coated tablets)

Rothrom® 20 (film-coated tablets)

Rivaroxaban

Contains sugar (each ROTHROM 10, ROTHROM 15 and ROTHROM 20 film-coated tablet contains 48,475 mg, 45 mg and 60 mg lactose monohydrate respectively.)

Read all of this leaflet carefully before you start taking ROTHROM

- 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.
- ROTHROM 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 ROTHROM is and what it is used for

2. What you need to know before you take ROTHROM

3. How to take ROTHROM

4. Possible side effects

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1. What ROTHROM is and what it is used for

ROTHROM contains rivaroxaban.

ROTHROM film-coated tablets belongs to a group of medicines called antithrombotic medicines. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

ROTHROM 10 film-coated tablets are used to prevent blood clots in the veins after major orthopaedic surgery of the lower limbs.

ROTHROM 15 and ROTHROM 20 film-coated tablets are used to:

- Prevent blood clots in your 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 in the blood vessels of your lungs (pulmonary embolism).
- To prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

2. What you need to know before you take ROTHROM

Do not take ROTHROM:

- If you are hypersensitive (allergic) to rivaroxaban or any of the inactive ingredients of ROTHROM (see “What ROTHROM is and what it is used for”).
- If you are currently bleeding such as bleeding in your brain or bleeding in your intestines or stomach.
- 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 your baby (see “Pregnancy, breastfeeding and fertility”).
- If you have a genetic bleeding disorder.
- If you have an autoimmune disorder called persistent triple positive antiphospholipid syndrome (APS), a disorder of the immune system that causes an increased risk of blood clots.

Warnings and precautions

Take special care with ROTHROM:

- If you have a prosthetic heart valve.
- If you have, or previously had, any of the following, you may be at an increased risk of bleeding:
    - Bleeding disorders.
    - Very high blood pressure not controlled by medical treatment.
    - Diseases of your gastrointestinal tract that might result in bleeding, e.g. inflammation or ulceration of your bowels, stomach or oesophagus (gullet), gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus) or tumours located in the stomach, bowels, genital tract or urinary tract.
    - A problem with the blood vessels in the back of your eyes (retinopathy).
    - Recent bleeding in your brain.
    - Abnormalities of your veins or arteries in your spine or brain.
    - Recent brain, spine or eye surgery.
    - Lung disease where your bronchi are permanently damaged, widened and thickened (bronchiectasis)
    - Previous bleeding from your lungs.
    - Liver or kidney problems.
- If you are taking other medicines to reduce blood clotting (e.g. clopidogrel, warfarin or enoxaparin) or non-steroidal anti-inflammatory medicines (NSAIDs) such as aspirin (see “Other medicines and ROTHROM”).
- If you have to go for an operation or surgical procedure, you must inform your doctor before your go for the operation, as you might have to stop your treatment with ROTHROM before you go for the procedure or operation.
- If your operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction). 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.

You must inform your doctor if any of the above applies to you.

If you have an autoimmune disorder called persistent triple positive antiphospholipid syndrome (APS) (see "Do not take ROTHROM") you should not use ROTHROM.

Other medicines and ROTHROM:

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

The following medicines may increase effects of ROTHROM:

- Medicines used to treat fungal infections such as ketoconazole, fluconazole, itraconazole, voriconazole or posaconazole.
- Medicines used in the treatment of HIV infection such as ritonavir.
- Medicines used to treat infections, such as clarithromycin or erythromycin.
- Medicines used to reduce blood clotting such as enoxaparin, clopidogrel, or warfarin. These medicines may increase the bleeding time with ROTHROM.
- Medicines used to treat pain and inflammation, such as naproxen and acetylsalicylic acid (aspirin).
- Dronedarone, a medicine to treat abnormal heartbeat.
- Some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)).

The following medicines may reduce the effects of ROTHROM:

- Medicines used to treat epilepsy such as phenytoin, carbamazepine and phenobarbitone.
- Herbal medicines used for depression such as St. John's Wort.
- Medicines used to treat infections such as rifampicin.

Pregnancy, breastfeeding and fertility

You must not take ROTHROM if you are pregnant of breastfeeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking ROTHROM.

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.

Driving and using machines

ROTHROM may make you feel dizzy and faint.

It is not always possible to predict to what extent ROTHROM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ROTHROM affects them.

ROTHROM contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ROTHROM.

3. How to take ROTHROM

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

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

Your doctor or pharmacist will tell you how long your treatment with ROTHROM will last.

If you have the impression that the effect of ROTHROM is too strong or too weak, tell your doctor or pharmacist.

Your doctor will determine your dose and duration of treatment based on your condition.

The usual dose of ROTHROM 10 mg to prevent blood clots in the veins after major orthopaedic surgery of the lower limbs, is one tablet daily.

The usual dose for prevention of stroke and systemic embolism is one ROTHROM 20 mg tablet daily.

The usual dose for deep vein thrombosis and pulmonary embolism treatment is one ROTHROM 15 mg tablet twice daily for the first three weeks followed by one ROTHROM 20 mg tablet once daily.

ROTHROM 10 can be taken with or without food. ROTHROM 15 and ROTHROM 20 should be taken with food.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

If you take more ROTHROM than you should

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

If you forget to take ROTHROM

Consult your doctor if you missed a dose of ROTHROM.

Your doctor will determine your missed dose and duration of treatment based on your condition.

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

If you stop taking ROTHROM

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

4. Possible side effects

ROTHROM can have side effects.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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

- A sudden life-threatening allergic reaction with swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, swelling under the skin.
- Skin rash or itching.
- Sudden drop in blood pressure or fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ROTHROM. 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:

- Signs of bleeding
  - Bleeding into the brain or inside the skull (symptoms can include headache, one-sided weakness, vomiting, seizures, decreased level of consciousness, and neck stiffness).
  - If you experience weakness, paleness, dizziness, headache, unexplained swelling, shortness of breath, chest pain or angina pectoris and unexplained shock (signs of bleeding risk).
  - Bruising on the skin.
- Signs of severe skin reactions
  - 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, blood abnormalities and systemic illness (DRESS syndrome).

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

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 (anaemia).

- Headache.
- Dizziness.
- Bleeding into the eye.
- Bleeding into the tissue or cavity of the body (haematoma).
- Low blood pressure (feeling of light-headedness).
- Bleeding from the nose (epistaxis).
- Coughing up blood (haemoptysis).
- Bleeding gums.
- Gastrointestinal bleeding.
- Indigestion and abdominal pain.
- Nausea, vomiting, diarrhoea and constipation.
- Bleeding from the skin or under the skin.
- Pain in the limbs.
- Presence of blood in the urine.
- Impaired function of the kidneys.
- Increased liver enzymes during blood tests.
- Abnormal heavy bleeding at menstruation.
- Fatigue and general decrease in energy.
- Fever.

Less frequent side effects:

- Blood tests may show increased platelet count (thrombocythaemia).
- Thrombocytopenia (low number of platelets, which are cells that help blood to clot).
- Allergic reactions.
- Bleeding into the brain or inside the skull.
- Temporary loss of consciousness (syncope).
- Fast heartbeat (tachycardia).
- Dry mouth.

- Vomiting of blood.
- Abnormal liver function and jaundice.
    - blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets.
    - cholestasis (decreased bile flow), hepatitis including hepatocellular injury (inflamed liver incl. liver injury).
- Allergic skin reactions.
- Bleeding into the joint spaces (haemarthrosis).
- Bleeding into muscles.
- Feeling unwell.
- Generalised swelling.

Side effects for which the frequency is not known:

- Bleeding from the kidneys.
- Fatal gastrointestinal ulcer bleeding.
- Compartment syndrome secondary to bleeding (a painful and potentially serious condition where muscle pressure reaches dangerous levels caused by bleeding or swelling within an enclosed bundle of muscles after an injury).
- Renal failure / acute renal failure secondary to a bleeding sufficient to cause hypoperfusion (loss of kidney function due to a sudden reduction of blood flow to the kidneys as a result of 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 ROTHROM.

Suspected adverse reactions can also be reported directly to the Holder of the Certificate of Registration (HCR) via Patientsafety.sacg@novartis.com.

5. How to store ROTHROM

- Store at or below 25 °C.
- Do not use after the expiry date stated on the label / carton / bottle.
- 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 THE REACH OF CHILDREN.**

6. Contents of the pack and other information

What ROTHROM contains

- The active substance is rivaroxaban.
- Each ROTHROM 10 film-coated tablet contains cellulose microcrystalline, croscarmellose sodium, hypromellose, lactose monohydrate (Granulac® 200), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate and opadry® orange 04F530012 (consisting of hypromellose, iron oxide red, macrogol, sunset yellow FCF, talc and titanium dioxide).

- Each ROTHROM 15 film-coated tablet contains cellulose microcrystalline, croscarmellose sodium, hypromellose, lactose monohydrate (Granulac® 200), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate and opadry® orange 04F530006 (consisting of hypromellose, iron oxide red, macrogol, sunset yellow FCF and titanium dioxide).

- Each ROTHROM 20 film-coated tablet contains cellulose microcrystalline, croscarmellose sodium, hypromellose, lactose monohydrate (Granulac® 200), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate and opadry® orange 04F530010 (consisting of hypromellose, iron oxide black, iron oxide red, iron oxide yellow, macrogol, sunset yellow FCF and titanium dioxide).

What ROTHROM looks like and contents of the pack

ROTHROM 10: Approximately 6 mm, peach coloured, round, biconvex film-coated tablets marked with “10” on one side.

ROTHROM 15: Approximately 6 mm, light orange coloured, round, biconvex film-coated tablets marked with “15” on one side.

ROTHROM 20: Approximately 7 mm, orange coloured, round, biconvex film-coated tablets marked with “20” on one side.

ROTHROM film-coated tablets are available in PVC/PVdC-Alu blister strips and in plastic (HDPE) containers with twist off caps with 2 g desiccant.

ROTHROM film-coated tablets are available in pack sizes of 10, 30 or 42 film-coated tablets.

The blister packs are packed into an outer cardboard carton.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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