

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

**WARNING: (A) INCREASED RISK OF BLOOD CLOTS IF YOU STOP TAKING XABANAR,
(B) SPINAL OR EPIDURAL BLOOD CLOTS (HEMATOMA)**

A. Increased risk of blood clots if you stop taking XABANAR:

If you stop taking any oral blood thinning medication too early, including XABANAR, you may have increased risk of forming a clot in your blood. If you have to stop taking XABANAR, your doctor may prescribe another blood thinning medicine to prevent a blood clot from forming.

B. Spinal or epidural blood clots (hematoma):

People who take XABANAR and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis).

Your risk of developing a spinal or epidural blood clot is higher if:

- a thin tube called an epidural catheter is placed in your back to give you certain medicine;
- you take nonsteroidal anti-inflammatory medicine (NSAIDs) or any other medicine to prevent blood from clotting;
- you have a history of difficult or repeated epidural or spinal punctures;
- you have a history of problems with your spine or have had surgery on your spine.

If you take XABANAR and receive spinal anesthesia or have a spinal puncture, your doctor should watch you closely for symptoms of spinal or epidural blood clots.

XABANAR 10 mg film-coated tablets

XABANAR 15 mg film-coated tablets

XABANAR 20 mg film-coated tablets

Rivaroxaban

Contains sugar: lactose monohydrate

Contains sodium

Read all of this leaflet carefully before you take XABANAR

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

1. What XABANAR is and what it is used for

XABANAR contains the active substance rivaroxaban. XABANAR 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.

XABANAR 10 mg is used to prevent blood clots in your veins after a major operation on your legs. For example, this could be an operation on your hip or knee. Your doctor has prescribed XABANAR 10 mg for you because after an operation you are at an increased risk of getting blood clots.

XABANAR 15 mg and XABANAR 20 mg 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 XABANAR

Do not take XABANAR

- if you are hypersensitive (allergic) to XABANAR or any of the other ingredients of XABANAR (listed in section 6).
- if you are bleeding excessively.
- if you have an inherited bleeding disorder (problem with the body's blood clotting process).
- 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.
- If you are treated for persistent triple positive antiphospholipid syndrome (APS). APS is a condition in which the immune system mistakenly creates antibodies that attack tissues in the body. These antibodies can cause blood clots to form in the arteries and veins.

Warnings and precautions

Take special care with XABANAR:

- 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 XABANAR”);
 - 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;
 - current or recent stomach ulcers (gastrointestinal ulcerations);
 - current or recent bleeding on the brain (intracranial / intracerebral haemorrhage);
 - shortly after operations of the brain, spine or eyes;
 - coronary artery disease with severe symptomatic heart failure.
- if you have a prosthetic heart valve (a one-way valve implanted into a person's heart to replace a heart valve that is not functioning properly).
 - 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 have an active cancer – this may also mean you have an increased risk of bleeding.
- An active cancer means that in the last 6 months you:
- have been diagnosed with cancer
 - had a relapse of cancer
 - were being treated for cancer

- if you have nonvalvular atrial fibrillation (a type of irregular heart rhythm that isn't caused by a problem with a heart valve, but caused by other things, such as high blood pressure or an overactive thyroid gland) and are undergoing a procedure called percutaneous coronary intervention or PCI, where a small balloon is used to reopen a blocked artery to increase blood flow and a small, permanent tube (stent) is inserted to keep the artery open long term.
- If you have a blood clot in the lung (pulmonary embolism or PE) and are considered to be high-risk (i.e. a condition known as hemodynamically unstable pulmonary embolism).
- if you experience any skin reactions, which may be severe and serious as a result of taking XABANAR. Patients appear to be at highest risk for these reactions early during treatment, especially in the first weeks of treatment.

If you need to have an operation

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

XABANAR 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 XABANAR

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. 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-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 and acenocoumarol).
- anti-inflammatory and pain-relieving medicines (e.g. naproxen or acetylsalicylic acid).
- dronedarone, a medicine to treat abnormal heartbeat.
- 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 XABANAR, because its effect may be increased. Your doctor will decide if you should be treated with XABANAR 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 (*Hypericum perforatum*), a herbal medicine used for depression.
- rifampicin, an antibiotic.

If any of the above apply to you, tell your doctor before taking XABANAR, because the effect of XABANAR may be reduced. Your doctor will decide if you should be treated with XABANAR 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 XABANAR.

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

Driving and using machines

XABANAR 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.

XABANAR contains lactose

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

XABANAR contains sodium

XABANAR contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take XABANAR

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

Always take XABANAR 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 veins after a hip or knee replacement operation: The recommended dose is one tablet XABANAR 10 mg once a day.

- To prevent blood clots in the brain (stroke) and other blood vessels in your body: The usual dose is one XABANAR 20 mg tablet once a day. If you have kidney problems, the dose may be reduced to one XABANAR 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 XABANAR 15 mg tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one XABANAR 20 mg tablet once a day.

Swallow the tablet preferably with water.

XABANAR 15 mg and 20 mg tablets have to be taken with food.

XABANAR 10 mg may be taken with or without food.

When to take XABANAR

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 XABANAR than you should

Taking too much XABANAR 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 XABANAR

- If you are taking one XABANAR 10 mg, 15 mg or 20 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 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 XABANAR 15 mg tablet twice a day and have missed a dose, take it as soon as you remember. Do not take more than two XABANAR 10 mg tablets in a single day. If you forget to take a dose you can take two XABANAR 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 XABANAR 15 mg tablet twice a day.

If you stop taking XABANAR

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

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

4. Possible side effects

XABANAR can have side effects.

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

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

If any of the following happens, stop taking XABANAR 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 XABANAR. 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

- long or excessive bleeding,
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain (angina pectoris). These may be signs of bleeding.

Sign of severe skin reaction

- 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).

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

Tell your doctor if you notice any of the following

Frequent

- 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,
- 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

- 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,
- oozing of blood or fluid from surgical wound,
- 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

- 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 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 XABANAR.

5. How to store XABANAR

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep in the original package 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 XABANAR contains

- The active substance is Rivaroxaban.

XABANAR 10 mg: Each film-coated tablet contains rivaroxaban 10 mg.

Contains sugar: lactose monohydrate 26,0 mg per tablet.

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

Contains sugar: lactose monohydrate 14,62 mg per tablet.

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

Contains sugar: lactose monohydrate 19,50 mg per tablet.

- The other ingredients are

Tablet core: croscarmellose sodium, hypromellose 2910, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate.

Film-coat (10 mg and 15 mg): hypromellose 2910, iron oxide red (E 172), macrogol/polyethylene glycol, titanium dioxide (E 171).

Film-coat (20 mg): iron oxide red (E 172), macrogol/polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide (E 171).

What XABANAR looks like and contents of the pack

XABANAR 10 mg: Round, light red, biconvex film-coated tablets having “A1” debossed on one side and plain on other side.

XABANAR 15 mg: Round, red, biconvex film-coated tablets having “A2” debossed on one side and plain on other side.

XABANAR 20 mg: Dark red coloured, oval shaped, biconvex film coated tablet with “A3” debossed on one side and plain on other side.

XABANAR film-coated tablets are packed in the following containers:

- Bottle pack

Round, white opaque high-density polyethylene (HDPE) container with child resistant closure.

- Alu-Alu blister pack

Cold forming blister aluminium foil as forming foil and aluminium foil with heat seal lacquer coat as lidding foil.

- Aluminium-PVC /PVdC blister pack

Plain aluminium foil heat seal lacquer and transparent PVC/PVdC film.

Pack size: 30's or 100's.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

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1686

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Not applicable

Registration numbers

XABANAR 10 mg: 56/8.2/0217

XABANAR 15 mg: 56/8.2/0218

XABANAR 20 mg: 56/8.2/0219

Access to the corresponding Professional Information

www.trinitypharma.co.za