

Xavir[®] 15 and 20 mg

rivaroxaban



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
 - If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- In this leaflet:**
1. What **Xavir[®]** is and what it is used for.
 2. Before you take **Xavir[®]**.
 3. How to take **Xavir[®]**.
 4. Possible side effects.
 5. How to store **Xavir[®]**.
 6. Further information.

1. What **Xavir[®]** is and what it is used for:

Pharmacotherapeutic group:

Xavir[®] contains the active substance rivaroxaban and belongs to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form clots.

Therapeutic indications:

Xavir[®] is used in adults to Prevent blood clots in brain (stroke) and other blood vessels in your body if you have a form of irregular heart rhythm called non-valvular atrial fibrillation.

2. Before you take **Xavir[®]**

Do not take **Xavir[®]**:

- If you are allergic to rivaroxaban or any of the other ingredients of this medicine
- 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 are pregnant or breast feeding

Do not take **Xavir[®]** and tell your doctor if any of these apply to you.

Take special care with **Xavir[®]**:

Talk to your doctor or pharmacist before taking **Xavir[®]**

- 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 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.
- 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 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 **Xavir[®]**. 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 **Xavir[®]** 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 **Xavir[®]** 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:

Xavir[®] is not recommended for people under 18 years of age. There is not enough information on its use in children and adolescents.

Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you can buy without a prescription, including herbal medicines. The effects of these medicines could be changed by **Xavir[®]** or they could change the effects of **Xavir[®]**.

- If you are taking:

- some medicines for fungal infections (e.g. ketoconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin.
 - 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 **Xavir[®]**, because the effect of **Xavir[®]** 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, phenobarbital).
- 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 **Xavir[®]**, because the effect of **Xavir[®]** may be reduced. Your doctor will decide, if you should be treated with **Xavir[®]** and if you should be kept under closer observation.

Pregnancy and breast-feeding:

Do not take **Xavir[®]** 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 **Xavir[®]**. 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:

Xavir[®] may cause dizziness (common side effect) or fainting (uncommon side effect). You should not drive or use machines if you are affected by these symptoms.

Important information about some of the ingredients of **Xavir[®]**:

Xavir[®] contains lactose; if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take **Xavir[®]**:

Always take **Xavir[®]** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take:

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

- the recommended dose is one Tablet **Xavir[®]** 20 mg tablet once a day.

If you have kidney problems, the dose may be reduced to one Tablet **Xavir[®]** 15 mg once a day.

If you need a procedure to treat blocked blood vessels in your heart (called a percutaneous coronary intervention- PCI with an insertion of a stent), there is limited evidence to reduce the dose to one tablet **Xavir[®]** 15 mg once a day (or to one tablet **Xavir[®]** 10 mg once a day in case your kidneys are not working properly) in addition to an antiplatelet medicinal product such as clopidogrel.

- 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 **Xavir[®]** 15 mg tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the recommended dose is one Tablet **Xavir[®]** 20 mg once a day.

If you have kidney problems and take one tablet **Xavir[®]** 20 mg once aday, your doctor may decide to reduce the dose for the treatment after 3 weeks to one tablet **Xavir[®]** 15 mg once aday if the risk for bleeding is greater than the risk for having another blood clot.

Swallow the tablet(s) preferably with water.

Take **Xavir[®]** together with a meal.

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take **Xavir[®]**.

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 **Xavir[®]** tablet through a stomach tube.

When to take **Xavir[®]**:

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 heart beat needs to be restored to normal by a procedure called cardioversion, take **Xavir[®]** at the times your doctor tells you.

If you take more **Xavir[®]** than you should:

Contact your doctor immediately if you have taken too many **Xavir[®]** tablets. Taking too much **Xavir[®]** increases the risk of bleeding.

If you forget to take **Xavir[®]**:

- 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 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 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 **Xavir[®]**:

Do not stop taking **Xavir[®]** without talking to your doctor first, because **Xavir[®]** 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:

Like all medicines, **Xavir[®]** can cause side effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), **Xavir[®]** 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:

- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis). The frequency of this side effect is very rare (up to 1 in 10,000).

- a drug reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome). The frequency of this side effect is very rare (up to 1 in 10,000).

Possible side effects which may be a sign of severe allergic reactions

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. The frequencies of these side effects are very rare (anaphylactic reactions, including anaphylactic shock; may affect up to 1 in 10,000 people) and uncommon (angioedema and allergic oedema; may affect up to 1 in 100 people).

Overall list of possible side effects: Common (may affect up to 1 in 10 people):

- 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 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).
- coughing up blood.
- bleeding from the skin or under the skin.
- 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.

Uncommon (may affect up to 1 in 100 people):

- 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.

Rare (may affect up to 1 in 1,000 people):

- 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).

Not known (frequency cannot be estimated from the available data):

- 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).

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

Reporting of suspected adverse reactions

Tel: 06-5632000

Website: www.jfda.jo

Smart phones application: Jordan fda

Paper reporting form: yellow card

5. How to store **Xavir[®]**:

- Keep out of the reach and sight of children.
- Do not store above 30°C.

- Do not use **Xavir[®]** after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information:

What **Xavir[®]** contains:

• **The active substance is:** Rivaroxaban. Each tablet contains 15 mg or 20mg of rivaroxaban.

The other ingredients are:

Tablet core: Microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, hypromellose, sodium laurilsulfate, magnesium stearate.

Tablet film coat: Opadry red (Macrogol, hypromellose, titanium dioxide, iron oxide red).

What **Xavir[®]** looks like and contents of the pack:

Pharmaceutical form:

Film coated tablets.

- Physical Description:

Xavir[®] 15mg: Red, round normal biconvex tablet with beveled edges engraved with "TQ" on one side and plain on the other.

Xavir[®] 20mg: Brown-red, round normal biconvex tablet with beveled edges engraved with "TQ" on one side and plain on the other.

Is available in the pack size of 28 and 30 tablets. Hospital packs are also available.

Xavir[®] is supplied in blisters packed in carton box with a folded leaflet.

Marketing Authorization Holder

Al-Taqaddom Pharmaceutical Industries.

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I-Xavir-XVR-LM0-R1/AE

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor
- Keep medicament out of the reach of children.

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