

Trade Name		Active Ingredient(s)&Strength(s) per tab.
Vaxato Film Coated Tablets		Rivaroxaban

Module 1- Administrative Information And Product Information

1.4.3 Patient information leaflet (PIL)

Refer to next page attached

Vaxato[®] 15mg Film Coated Tablets

Vaxato[®] 20mg Film Coated Tablets

Rivaroxaban

PATIENT INFORMATION LEAFLET

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 further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. 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 your pharmacist.(See Section 4)

- What in this leaflet:**
1. What **Vaxato**[®] is and what it is used for
 2. Before you take **Vaxato**[®]
 3. How to take **Vaxato**[®]
 4. Possible side effects
 5. How to store **Vaxato**[®]
 6. Further information

1. WHAT VAXATO[®] IS AND WHAT IT IS USED FOR

Vaxato[®] contains the active substance rivaroxaban and 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.
- Treat blood clots in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), and to prevent blood clots from re-occurring in the blood vessels of your legs and/or lungs.

Vaxato[®] 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.

2. BEFORE YOU TAKE VAXATO[®]

Do not take Vaxato[®]:

- If you are allergic to Rivaroxaban or any of the other ingredients of this medicine (listed in section 6).
- If you have 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.

Don not take Vaxato[®] and tell your doctor if any of this apply to you.

Warning and Precautions:

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

Take special care with Vaxato[®]:

- If you have an increased risk of bleeding, as could be the case in situation such as:
 - Severe kidney disease, since your kidney function may affect the amount of the 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 Vaxato[®]).
 - Bleeding disorders.
 - Very high blood pressure, not controlled by medical treatment.
 - Disease 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 gastro-esophageal reflux disease “disease where stomach acid goes upward into the esophagus”).
 - A problem with blood vessels in the back of the 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 lung is planned.

If any of the above apply to you, tell your doctor before you take **Vaxato**[®], 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 **Vaxato**[®] 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 anesthesia or pain reduction):
- It is very important to take **Vaxato**[®] before and after 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 baldder, after the end of anesthesia, because urgent care is necessary.

Children and adolescents:

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

Other medicine and Vaxato[®]:

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 (SNRI)).

If any of the above apply to you, tell your doctor before taking **Vaxato**[®], because the effect of **Vaxato**[®] 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 preventive 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 **Vaxato**[®], because the effect of **Vaxato**[®] may be reduced. Your doctor will decide, if you should be treated with **Vaxato**[®] and if you should be kept under closer observation.

Pregnancy and breastfeeding:

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

Vaxato[®] may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4 ‘Possible side effects’). You should not drive or use machines if you are affected by these symptoms.

3. HOW TO TAKE VAXATO[®]

Always take this medicine exactly as your doctor has told you. 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 (**Vaxato**[®] 20mg) once a day.

If you have kidney problems, the dose may be reduced to one tablet (**Vaxato**[®] 15mg) once a day.

- If you need a procedure to treat blocked blood vessels in your heart (called percutaneous coronary intervention – PCI with an insertion of stent), there is limited evidence to reduce the dose to one tablet **Vaxato**[®]15mg once a day (or to one tablet **Vaxato**[®] 10mg once a day in case your kidneys are not working properly), in addition to antiplatelets 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 daily dose is one tablet **Vaxato**[®] 15mg twice a day for the first 3 weeks, for treatment after 3 weeks, the recommended dose is one tablet **Vaxato**[®] 20mg once a day.

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

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

Swallow the tablet(s) preferably with water.

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

If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take **Vaxato**[®]. 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 **Vaxato**[®] tablet through a stomach tube.

When to take Vaxato[®]

Take a 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 brain (stroke) and other blood vessel in your body: If your heart beat needs to be restored to normal by a procedure called (cardioversion), take **Vaxato**[®] at times your doctor tells you.

If you take more Vaxato[®] than you should:

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

If you forget to take Vaxato[®]:

- If you are taking one 20mg tablet or one 15mg tablet once a day and you 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 15mg tablet twice a day and you have missed a dose, take it as soon as you remember it. Do not take more than two 15mg tablets in a single day. If you forget to take a dose, you can take two 15mg tablets at the same time to get a total of two tablets (30mg) on one day. On the following day you should carry on taking one 15 mg tablets twice a day.

If you stop taking Vaxato[®]:

Do not stop taking **Vaxato**[®] without talking to your doctor first, because **Vaxato**[®] 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, **Vaxato**[®] can cause side effects, although not everybody gets them.

Like other similar medicines (antithrombotic agents), **Vaxato**[®] 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 cause 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 tissues or a cavity of the body (hematoma, 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, diarrhea.
- 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 (deceased 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 into your leg artery (pseudoaneurysm).

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

- Kidney failure after a severe bleeding.
- Increased pressure within the 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.

5. HOW TO STORE VAXATO[®]

Keep this medicine out of the reach and sight of children.

Do not Store above 30° C.

Store **Vaxato**[®] in the original container.

Do not take **Vaxato**[®] after the expiry date which is stated on the carton and the strip. The expiry 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 Vaxato[®] contains

The active substance of Vaxato[®] **15mg:**

Rivaroxaban 15mg

The active substance of Vaxato[®] **20mg:**

Rivaroxaban 20mg

The inactive substances:

Tablet Core:

Microcrystalline cellulose pH102, Mannitol, Croscarmellose sodium, Sodium Lauryl Sulfate, Citric Acid Anhydrous, Magnesium Stearate.

Tablet Coat:

Opadry red

What Vaxato[®] **Looks like and contents of the pack?**

Carton box containing 1 or 2 or 3 (AL/AL.) Strips, each strip of 10 film coated tablets and a leaflet.

Marketing Authorization Holder and Manufacturer:

LIPTIS FOR PHARMACEUTICALS AND MEDICAL PRODUCTS

Plot no. B/2, 6th Industrial zone, 6th of October City, Egypt.

Date of approval this leaflet

(mm/yy) (Version No.)

This is a Medicament

- Medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use, and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are drug expert in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting you doctor.
- Leave the medicaments out of reach of children.

