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## **Safety Information Card for Patients Under Anticoagulant Treatment with Rivaroxaban Propharm**

**Rivaroxaban Propharm 10 mg**

**Rivaroxaban Propharm 15 mg**

**Rivaroxaban Propharm 20 mg**

Keep this card with you at all times.  
Present this card to every doctor or dentist at the beginning of the visit.

**The patient carrying this card is being treated with Rivaroxaban Propharm**

Name \_\_\_\_\_  
Address \_\_\_\_\_  
Date of birth \_\_\_\_\_ Weight \_\_\_\_\_  
Information regarding concomitant medications and diseases \_\_\_\_\_

**Information in case of emergency**

**In case of emergency, please notify:**

Doctor's name \_\_\_\_\_ Doctor's phone \_\_\_\_\_

**Please also notify:**

Name \_\_\_\_\_ Relationship \_\_\_\_\_

Phone \_\_\_\_\_

Emergency phone (Clinic/first aid) \_\_\_\_\_

**Information regarding use of the medicine**

Treatment start date \_\_\_\_\_

Indication \_\_\_\_\_

Dosage and administration regimen \_\_\_\_\_

Renal function at the beginning of treatment (creatinine clearance ml/min)

**Information for healthcare providers:**

INR values are not suitable for assessing the anticoagulant activity of Rivaroxaban Propharm and therefore should not be used for this purpose.

### Information on anticoagulants and guidance for the patient

- ◆ Rivaroxaban Propharm is a blood thinner, which protects you against development of dangerous blood clots.
- ◆ Rivaroxaban Propharm must be taken exactly as prescribed by your doctor. To ensure optimal protection from blood clots you should strictly comply with the administration schedule as recommended by your doctor and never skip a dose, unless instructed by the doctor.
- ◆ You must not stop taking Rivaroxaban Propharm without first talking to your doctor as your risk of blood clots may increase.

### Taking this medicine with food:

To ensure optimal treatment effectiveness:

- ◆ **Rivaroxaban Propharm 20 mg** must be taken with food.
- ◆ **Rivaroxaban Propharm 15 mg** must be taken with food.
- ◆ **Rivaroxaban Propharm 10 mg** can be taken with or without food.

The tablet should be swallowed with water. If you have difficulty swallowing the tablet whole, the tablet can be crushed and mixed with water or apple puree immediately before taking it. For Rivaroxaban Propharm 15 mg and 20 mg, the crushed medicine should then be immediately followed by food intake.

**If you forgot to take Rivaroxaban Propharm at the required time:**

- ◆ Rivaroxaban Propharm at a dosage of 10/15/20 mg once daily – you should take a dose as soon as you remember. However, you should never take two doses on the same day!
- ◆ Rivaroxaban Propharm at a dosage of 15 mg twice a day - [for the first 3 weeks for Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) treatment] - take a dose as soon as you remember. Do not take more than two 15 mg tablets in a single day. Two 15 mg tablets can be taken together to obtain a dosage of 30 mg per day. On the following day, carry on taking one 15 mg tablet twice a day.

\*In case of doubt, consult your doctor.

- ◆ Tell the doctor about any other medicine that you are currently taking, have recently taken or intend to start taking, before you start treatment with Rivaroxaban Propharm. This instruction also includes non-prescription medicines, including non-steroidal anti-inflammatory drugs (NSAIDs) and nutritional supplements.
- ◆ Inform your doctor about Rivaroxaban Propharm intake prior to any surgery or invasive procedure, including dental treatments.
- ◆ When taking an anticoagulant such as Rivaroxaban Propharm, you should be aware of its possible side effects.
  - For a full list of side-effects please refer to the patient package insert.
  - Bleeding is the most common side effect.
  - Do not start taking Rivaroxaban Propharm if you know you are at risk of bleeding without first discussing this with your doctor.

**Tell your doctor straight away if you have any signs or symptoms that could indicate bleeding, such as the following:**

- Pain
- Paleness
- Unexplained swelling or discomfort
- Headache, dizziness, tiredness or exceptional weakness
- Breathlessness
- Chest pain or angina pectoris
- Unusual bruising, nosebleeds, bleeding of gums, bleeding from cuts that take a long time to stop
- Vaginal bleeding or menstrual flow that is heavier than normal
- Blood in the urine that may be pink or brown; red or black stools
- Coughing up blood, or vomiting blood or material that looks like coffee grounds

**If you are at increased risk of bleeding, you should discuss this/consult with your doctor. The main risk factors for bleeding include, among others:**

- Moderate or severe kidney disease
- Liver impairment
- If you are taking other medicines which affect blood clotting, e.g., non-steroidal anti-inflammatory drugs, aspirin and other anticoagulants
- Very high blood pressure, uncontrolled
- You are suffering from bleedings
- Disease of the stomach or bowel that might result in bleeding, e.g., inflammation of the bowel or stomach or inflammation of the esophagus due to, for example, gastroesophageal reflux
- Retinopathy
- Bronchiectasis or previous bleeding from the lung

### Reporting side-effects

Side-effects can be reported to the Ministry of Health using the portal for reporting side effects which can be found on the Ministry of Health website: [www.health.gov.il](http://www.health.gov.il) or via the link: <https://sideeffects.health.gov.il>

Additionally, side-effects and product quality complaints can be reported to the registration holder:

E-mail: [safety@medicalix.com](mailto:safety@medicalix.com)

Telephone: 1-800-200-047

Fax: 073-2638521

For additional information please refer to the Patient Package Insert. In case of any questions, please refer to your doctor.

This card was approved according to the guidelines of the ministry of health on 09.2024.