

**Safety Information Card for Patients
Under Anticoagulant Treatment with Rivaroxaban Taro**

Rivaroxaban Taro 2.5 mg

Rivaroxaban Taro 10 mg

Rivaroxaban Taro 15 mg

Rivaroxaban Taro 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 under anticoagulant treatment
with Rivaroxaban Taro**

Name _____

Address _____

Date of birth _____ Weight _____

Information regarding concomitant diseases and medications

Information in case of emergency

In case of emergency, please inform the treating doctor

Telephone _____

Please also notify:

Name _____ Relationship _____

Telephone _____

Emergency phone (clinic/first aid) _____

Information regarding use of the medicine

Treatment start date _____

Indication _____

Dosage and administration regimen _____

Renal function at treatment onset (creatinine clearance mL/min)

Information for healthcare providers:

Measuring INR is not suitable for assessment of the anticoagulant activity of Rivaroxaban Taro and should therefore not be used for this purpose.

Information on anticoagulants and guidance for the patient

- ❖ The anticoagulant, Rivaroxaban Taro, is a blood thinner, which protects you from the development of dangerous blood clots.
- ❖ Rivaroxaban Taro 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 do not skip any dose, unless instructed by your doctor.
- ❖ Do not stop taking Rivaroxaban Taro without consulting your doctor, as your risk of blood clots may increase.

Administration with food:

To ensure maximum treatment effectiveness:

- ❖ **Rivaroxaban Taro 20 mg** - must be taken with food.
- ❖ **Rivaroxaban Taro 15 mg** - must be taken with food.
- ❖ **Rivaroxaban Taro 10 mg** - can be taken with or without food.
- ❖ **Rivaroxaban Taro 2.5 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 may be crushed and mixed with water or apple puree immediately before it is taken. At dosages of 15/20 mg, eat immediately after taking the crushed medicine.

If you forget to take Rivaroxaban Taro at the required time:

Rivaroxaban Taro 10/15/20 mg:

- ❖ At a dosage of 10/15/20 mg once a day - take a dose as soon as you remember, but under no circumstances should you take two doses on the same day!
- ❖ At a dosage of 15 mg twice a day [for the first three weeks for deep vein thrombosis (DVT) or pulmonary embolism (PE) treatment] - take a dose as soon as you remember. Do not take more than two 15 mg tablets on one day. You may take two 15 mg tablets together to get a dose of 30 mg on one day. On the following day, you should carry on taking one 15 mg tablet twice a day.

* In case of doubt, consult your doctor.

Rivaroxaban Taro 2.5 mg:

- ❖ While taking Rivaroxaban Taro 2.5 mg - take the next dose at the usual time and consult your doctor. Do not take a double dose to make up for a forgotten dose.
- ❖ 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 Taro.
This instruction also includes non-prescription medicines, including non-steroidal anti-inflammatory drugs (NSAIDs) and nutritional supplements.
- ❖ Inform your doctor about Rivaroxaban Taro intake prior to any surgery or invasive procedure, including dental treatments.
- ❖ When taking an anticoagulant such as Rivaroxaban Taro, 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 Taro if you know you are at risk of bleeding without first discussing this with your doctor.

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

- 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 abnormally heavy
- 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 your doctor.

The main risk factors for bleeding include, among others:

- Moderate or severe kidney disease
- Liver disturbance
- Medicines that affect blood clotting, e.g., non-steroidal anti-inflammatory drugs, aspirin and other anticoagulants
- Severe and uncontrolled high blood pressure
- You are suffering from bleeding
- Diseases of the stomach or bowel that might result in bleeding, e.g., inflammation of the bowel or stomach, or inflammation of the oesophagus due to, for example, gastroesophageal reflux
- Retinopathy
- Bronchiectasis or previous bleeding from the lung

Additional risk factors for bleeding for patients taking Rivaroxaban Taro 2.5 mg

- Age 75 years or older
- Weight of 60 kg or less
- Coronary artery disease with severe symptomatic heart failure

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 homepage of the Ministry of Health website:

www.health.gov.il

Or via the link: <https://sideeffects.health.gov.il>

Additionally, you can report directly to Taro by e-mail:

drug.safety@taro.com

or by phone: 1-800-46-46-64

For additional information, refer to the patient package insert.
In case of any questions, please refer to your treating doctor.
This card was approved according to Ministry of Health instructions in
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