

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) -  
1986**

This medicine is dispensed with a doctor's prescription only

**Rivaroxaban Taro 15 mg  
Rivaroxaban Taro 20 mg  
Film-coated tablets**

**Active ingredient**

Each tablet contains:

rivaroxaban 15 mg

rivaroxaban 20 mg

Inactive ingredients and allergens in the medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

In addition to the leaflet, Rivaroxaban Taro also has a patient safety information card. This card contains important safety information that you need to know and that you should follow before starting and during treatment with Rivaroxaban Taro. Carefully read the patient safety information card and patient information leaflet before using this medicine.  
Keep the card and the leaflet in case you need to read it again.

**1. What is this medicine intended for?**

Rivaroxaban Taro is intended for the following conditions in adults:

- Prevention of blood clots in the brain (stroke) and in other blood vessels in the body in patients with an irregular heart rate called non-valvular atrial fibrillation and from one or more of the following risk factors: congestive heart failure, hypertension, age ( $\geq 75$  years), diabetes mellitus, prior stroke or transient ischaemic attack.
- Treatment of blood clots in leg veins (deep vein thrombosis, DVT) and in the blood vessels of the lungs (pulmonary embolism, PE), and prevention of recurrent blood clots in the blood vessels of the legs and/or lungs.

Rivaroxaban Taro is intended for children and adolescents below 18 years of age weighing 30 kg or more for:

- Treatment of blood clots and prevention of reoccurrence of blood clots in the veins or blood vessels of the lungs, following initial treatment of at least 5 days with injectable medicines used to treat blood clots.

**Therapeutic group:** Rivaroxaban belongs to a group of medicines called anticoagulants and works by blocking a blood clotting factor (factor Xa), thus reducing the tendency to form blood clots.

## **2. Before using this medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to rivaroxaban or to any of the other ingredients in this medicine. For the list of inactive ingredients, see section 6 'Additional information'.
- You are suffering from excessive bleeding.
- 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).
- 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.
- You have a liver disease which leads to an increased risk of bleeding.
- You are pregnant or breastfeeding.

Do not take Rivaroxaban Taro and tell your doctor if any of the conditions described above apply to you.

### **Special warnings about using this medicine**

Talk to your doctor or pharmacist before taking Rivaroxaban Taro.

### **Take special care when using Rivaroxaban Taro. Before treatment with Rivaroxaban Taro, tell your doctor if:**

- You have an increased risk of bleeding, as could be the case in situations such as:
  - severe kidney disease in adults, and moderate to severe kidney disease in children and adolescents, since your kidney function may affect the amount of medicine that works in your body. (See section 3 'How to use this medicine?' regarding the recommended dosage in case of kidney disease).
  - you are taking other medicines to prevent blood clotting (e.g. warfarin, dabigatran, apixaban or heparin), when changing from one anticoagulant to another or while getting heparin through a venous or arterial line to keep it open (see section 2 'Drug interactions').
  - you suffer from bleeding.
  - very high blood pressure, not controlled by medication therapy.
  - disease of the stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or inflammation of the oesophagus, e.g. due to gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus) or tumours located in the stomach or bowels, genital tract or urinary tract.

- problems with the blood vessels in the retina (retinopathy).
- a lung disease where the bronchi are widened and filled with pus (bronchiectasis), or previous bleeding from the lung.
- You have a prosthetic heart valve.
- 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.
- Your doctor determined 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 conditions apply to you, tell your doctor** before you take the medicine. Your doctor will decide if you should be treated with Rivaroxaban Taro and if you require close observation.

- If your doctor thinks that you are at increased risk of developing stomach or bowel ulcers, the doctor may also give you a preventative treatment.

**If you are due to undergo surgery or an invasive procedure**

- It is very important to take Rivaroxaban Taro before and after the operation or the invasive procedure exactly at the times scheduled for you 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 Rivaroxaban Taro before and after the injection or removal of the catheter exactly at the times scheduled for you by your doctor.
  - Tell your doctor immediately if you get numbness or weakness of the legs or problems with the bowel or bladder after the anaesthesia has worn off, because urgent medical intervention is necessary.

**Children and adolescents**

This medicine is not recommended for children and adolescents weighing less than 30 kg.

There is insufficient information about use in children and adolescents in the adult indications.

**Interactions with other medicines**

**If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- certain medicines for fungal infections (e.g. fluconazole, itraconazole, voriconazole, posaconazole), unless they are intended only for application to the skin.
- tablets that contain ketoconazole for treatment of Cushing's syndrome - a condition in which the body produces an excess of cortisol.
- certain medicines for bacterial infections (e.g. clarithromycin, erythromycin).
- certain antiviral medicines to treat AIDS virus (HIV) infections (e.g. ritonavir).
- other anticoagulants (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 [aspirin]).
- dronedarone, a medicine to treat an irregular heartbeat.
- certain medicines to treat depression (selective serotonin reuptake inhibitors [SSRIs] or serotonin norepinephrine reuptake inhibitors [SNRIs]).

**If any of the above conditions apply to you, tell your doctor** before taking the medicine, because these medicines may increase the effect of Rivaroxaban Taro. Your doctor will decide if you should take Rivaroxaban Taro and if close medical observation is necessary.

**Additionally, inform your doctor or pharmacist if you are taking:**

- certain medicines for treatment of epilepsy (e.g. phenytoin, carbamazepine, phenobarbital).
- St John's Wort (Hypericum), a herbal product used for depression.
- rifampicin (antibiotic).

**If any of the above conditions apply to you, tell your doctor** before taking the medicine, because these medicines may reduce the effect of Rivaroxaban Taro. Your doctor will decide if you should take Rivaroxaban Taro and if close medical observation is necessary.

**Using this medicine and food**

This medicine must be taken with food and preferably with water.

**Pregnancy, breastfeeding and fertility**

Do not take Rivaroxaban Taro if you are pregnant or breastfeeding.

If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking Rivaroxaban Taro.

If you become pregnant while you are taking this medicine, tell your doctor immediately, who will decide on your continued treatment.

**Driving and using machines**

Rivaroxaban Taro may cause dizziness (a common side effect) or fainting (an uncommon side effect) (see section 4 'Side effects'). You should not drive, ride a bicycle, use any tools or operate machines while using Rivaroxaban Taro if you are affected by these symptoms.

**Important information about some of this medicine's ingredients**

This medicine contains lactose and sodium.

If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before you start taking Rivaroxaban Taro.

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

**3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

### Adults

- To prevent blood clots in the brain (stroke) and other blood vessels in the body, the recommended dosage is usually one 20 mg tablet once a day.
- If you have impaired kidney function, your dosage may be reduced to one 15 mg tablet once a day.
- If you need to undergo a procedure to treat blockage of the blood vessels in the heart (a procedure called percutaneous coronary intervention - PCI with insertion of a stent), there is limited information about reducing the dosage to one tablet of Rivaroxaban Taro 15 mg once a day in addition to a platelet aggregation inhibitor such as clopidogrel.
- To treat blood clots in the leg veins and in the blood vessels in the lungs and to prevent recurrence of blood clots, the recommended dosage is usually one 15 mg tablet twice a day for the first 3 weeks, and then one 20 mg tablet once a day. After completing at least 6 months of treatment, your doctor may decide to continue the treatment with Rivaroxaban Taro 10 mg, one tablet a day.
- If you have impaired kidney function and take Rivaroxaban Taro 20 mg once a day, your doctor may decide to reduce the dosage after 3 weeks to one 15 mg tablet once a day, if the risk of bleeding is greater than the risk of developing another blood clot.

### Children and adolescents

The dosage of Rivaroxaban depends on the body weight, and will be calculated by the doctor.

- The recommended dosage for children and adolescents **weighing between 30 kg and less than 50 kg** is one **Rivaroxaban 15 mg tablet** once a day.
- The recommended dosage for children and adolescents **weighing 50 kg or more** is one **Rivaroxaban 20 mg tablet** once a day.

Take the Rivaroxaban dose with a drink (e.g. water or juice) during a meal. Take the tablets every day at the same time. Consider setting an alarm to remind you. For parents or caregivers: please observe the child to ensure that the full dose is taken.

Since Rivaroxaban dosage is based on the body weight, it is important to attend scheduled doctor's visits because the dosage may need to be adjusted as the body weight changes.

**Never adjust the dosage of Rivaroxaban by yourself.** The doctor will adjust the dosage if necessary.

Do not split the tablet in an attempt to provide a fraction of the tablet dose. If a lower dosage is required, use **Rivaroxaban** 1 mg/ml granules for oral suspension. For children and adolescents who are unable to swallow tablets whole, use Rivaroxaban 1 mg/ml granules for oral suspension. If Rivaroxaban 1 mg/ml granules for oral suspension is not available, you may crush the tablet and mix with water or apple puree immediately before taking it. Eat immediately after taking the

crushed medicine. If necessary, your doctor may give you the crushed Rivaroxaban tablet through a stomach feeding tube.

**Do not exceed the recommended dose.**

Treatment duration

Take Rivaroxaban Taro every day until your doctor tells you to stop.  
Your doctor will decide how long you should be treated with the medicine.

Method of administration

This medicine must be taken with food and swallowing the tablet with water is recommended. If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Rivaroxaban Taro.

The tablet may be crushed and mixed with water or apple puree immediately before it is taken.

Eat immediately after taking the crushed medicine.

If necessary, your doctor may also give you crushed Rivaroxaban Taro through a stomach feeding tube.

There is no information about splitting/chewing.

Taking the medicine at the same time every day will help you remember to take it.

**If you spit the dose or vomit**

- If less than 30 minutes have passed after Rivaroxaban intake, take a new dose.
- If more than 30 minutes have passed after Rivaroxaban intake, **do not** take a new dose. In this case, take the next Rivaroxaban dose at the usual time.

Contact your doctor if you repeatedly spit the dose or vomit after taking Rivaroxaban.

**If you have accidentally taken a higher dose**, contact your doctor immediately.

Taking too much Rivaroxaban Taro increases the risk of bleeding.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine at the scheduled time**

Adults, children and adolescents:

- At a dosage of one Rivaroxaban Taro 15 mg or Rivaroxaban Taro 20 mg tablet once a day, take a dose as soon as you remember, but under no circumstances should you take a double dose or two doses on the same day! Take the next dose the following day and then once a day, as usual, and consult your doctor.

Adults:

- At a dosage of one 15 mg tablet twice a day, 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.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor, because Rivaroxaban Taro treats and prevents serious conditions.

**If you stop taking this medicine**, you are hurting its therapeutic and preventative ability.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, using Rivaroxaban Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Like other similar medicines for reduction of blood clot formation, Rivaroxaban Taro 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.

**Contact your doctor immediately if you or your child experience any of the following side effects:**

##### **Signs of bleeding:**

- bleeding into the brain or inside the skull (symptoms can include headache, one-sided weakness, vomiting, seizures, decreased level of consciousness, and neck stiffness). This is a serious medical emergency. Seek medical attention immediately!
- long or excessive bleeding.
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris.

Your doctor will decide whether close observation or a change in treatment is required.

##### **Signs of a 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, blood abnormalities and systemic illness (DRESS syndrome). These side effects are very rare (up to 1 in 10,000 users).

##### **Signs of severe allergic reactions:**

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties; sudden drop in blood pressure. Severe allergic reactions are very rare (anaphylactic reactions, including anaphylactic shock, may affect up to 1 in 10,000 users) and uncommon (angioedema and allergic oedema may affect up to 1 in 100 users).

#### **Additional side effects reported in adults, children and adolescents**

**Common side effects (may affect up to 1 in 10 users):**

- reduction in red blood cells which can lead to paleness, weakness or breathlessness
- bleeding in the stomach or bowel, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nosebleed, bleeding in the gums
- bleeding into the eye (including bleeding from the whites of the eyes)
- bleeding into a tissue or a cavity of the body (localized haematoma, bruising)
- coughing up blood
- bleeding from the skin or under the skin
- bleeding following an operation
- oozing of blood or fluid from a surgical wound
- swelling of the limbs
- pain in the limbs
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever
- stomach ache, indigestion, nausea or vomiting, 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 certain liver enzymes

**Uncommon side effects (may affect up to 1 in 100 users):**

- bleeding into the brain or inside the skull (see above, 'signs of bleeding')
- bleeding into a joint causing pain and swelling
- thrombocytopenia (low number of blood 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 indicate an increase in bilirubin, certain pancreatic or liver enzymes or in the number of platelets
- fainting
- general feeling of being unwell
- faster heartbeat
- dry mouth
- hives (urticaria)

**Rare side effects (may affect up to 1 in 1,000 users):**

- bleeding into a muscle
- cholestasis (decreased bile flow), hepatitis including hepatocellular injury (inflamed liver including liver injury)
- yellowing of the skin and eye (jaundice)
- localised swelling
- Localized collection of blood (haematoma) in the groin as a complication of a cardiac procedure where a catheter is inserted into the leg artery

**Very rare side effects (may affect up to 1 in 10,000 people)**



- accumulation of eosinophils, a type of white granulocytic blood cells causing inflammation in the lungs (eosinophilic pneumonia).

**Side effects of unknown frequency (the frequency of these effects has not been established yet):**

- kidney failure after a severe bleeding
- increased pressure within muscles of the legs or arms after bleeding, which causes pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after bleeding)

**Side effects in children and adolescents**

**In general, the side effects observed in children and adolescents treated with Rivaroxaban were similar to those observed in adults and were primarily mild to moderate in severity.**

**Side effects that were observed more often in children and adolescents:**

**Very common side effects (may affect more than 1 in 10 users):**

- headache
- fever
- nosebleed
- vomiting

**Common side effects (may affect up to 1 in 10 users):**

- increased heartbeat
- blood tests may indicate an increase in bilirubin (bile pigment)
- thrombocytopenia (low number of platelets, which are cells that help blood to clot)
- heavy menstrual bleeding

**Uncommon side effects (may affect up to 1 in 100 users):**

- blood tests may indicate an increase in a sub-category of bilirubin (direct bilirubin, bile pigment)

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

**Storage conditions**

- Store below 25°C.
- Crushed tablets are stable in water or apple puree for up to 4 hours.
- Do not throw away the medicine via wastewater or household waste. Ask your pharmacist about how to throw away this medicine (medicines you no longer use). These measures will help protect the environment.

**6. Additional information**

**In addition to the active ingredient, this medicine also contains:**

lactose monohydrate, microcrystalline cellulose, hydroxypropyl cellulose, hypromellose, croscarmellose sodium, magnesium stearate, sodium lauryl sulfate, film coating (contains: hypromellose, lactose monohydrate, iron oxide red, macrogol, titanium dioxide).

Additionally, the film coating of Rivaroxaban Taro 15 mg tablets contains:

Carmine

**What the medicine looks like and contents of the pack:**

Rivaroxaban Taro 15 mg: round, red film-coated tablets. One side is imprinted with “□” and the other with “15”.

Rivaroxaban Taro 20 mg: round, dark red film-coated tablets. One side is imprinted with “□” and the other with “20”.

The medicine is marketed in a pack containing 30 film-coated tablets.

**Registration holder's and manufacturer's name and address:**

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

**Revised in October 2023 according to MOH guidelines.**

**Registration number of the medicine in the Ministry of Health National Drug Registry:**

Rivaroxaban Taro 15 mg: 162-54-35229-00

Rivaroxaban Taro 20 mg: 162-55-35230-00