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

This medicine is dispensed with a doctor's prescription only

Rivaroxaban Taro 10 mg
Film-coated tablets

Active ingredient
Each tablet contains:
rivaroxaban 10 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 you start 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 10 mg is intended for:
- Prevention of the development of blood clots in the veins in adults after an elective hip or knee replacement operation.
- Prevention of re-ocurrence of blood clots in leg veins (deep vein thrombosis, DVT) and in the blood vessels of the lungs (pulmonary embolism, PE), after completing 6 months of treatment for deep vein thrombosis or previous pulmonary embolism.

Therapeutic group: rivaroxaban belongs to a group of medicines called antithrombotic agents and works by blocking a blood clotting factor (factor Xa) and thus reducing the tendency of the blood to form 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 a list of the inactive ingredients, see section 6 'Additional information'.
- you are bleeding excessively.
- 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 breast-feeding.

Do not take Rivaroxaban Taro 10 mg 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 10 mg.

Take special care when using Rivaroxaban Taro 10 mg. Before treatment with Rivaroxaban Taro 10 mg, tell your doctor if:
- you have an increased risk of bleeding, as could be the case in situations such as:
  - moderate or severe kidney disease, since your kidney function may affect the amount of medicine that works in your body.
  - 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.
  - diseases of your 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 or genital tract or urinary tract.
  - problems with the blood vessels in your retina (retinopathy).
  - a lung disease where your bronchi are widened and filled with pus (bronchiectasis), or previous bleeding from your 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 a surgical procedure or another treatment 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 10 mg and if you require close observation.

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

If you are due to undergo surgery
- It is very important to take Rivaroxaban Taro 10 mg before and after the operation 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 10 mg exactly at the times scheduled for you 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 medical intervention is necessary.

Children and adolescents
This medicine is not intended for children and adolescents below 18 years of age. There is insufficient information about use in children and adolescents.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- some 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.
- some medicines for bacterial infections (e.g. clarithromycin, erythromycin).
- some antiviral 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 [aspirin]).
- dronedarone, a medicine to treat an irregular heart beat.
- some 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 10 mg. Your doctor will decide if you should take Rivaroxaban Taro 10 mg and if you should be kept under close medical observation.

Additionally, inform your doctor or pharmacist if you are taking:
- some 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 10 mg. Your doctor will decide if you should take Rivaroxaban Taro 10 mg and if you should be kept under close medical observation.

Using this medicine and food
Rivaroxaban Taro 10 mg may be taken with or without food.

Pregnancy, breast-feeding and fertility
Do not take Rivaroxaban Taro 10 mg 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 Rivaroxaban Taro 10 mg. 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 10 mg may cause dizziness (common side effect) or fainting (uncommon side effect) (see section 4, 'Side effects'). You should not drive, ride a bicycle or use any tools or operate machines while using Rivaroxaban Taro 10 mg 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 some sugars, contact your doctor before you start taking Rivaroxaban Taro 10 mg.
This medicine contains less than 1 mmol sodium (23 mg) 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.

- To prevent development of blood clots in the veins after a hip or knee replacement operation, the recommended dose is usually one tablet (10 mg) once a day. Take the first tablet 6-10 hours after your operation, if your doctor determined that your condition is stable. Then take one tablet once a day until your doctor instructs you to stop.
- To prevent blood clots from re-occurring in your leg veins (deep vein thrombosis) and in the blood vessels in your lungs (pulmonary embolism) after completing 6 months of treatment for deep vein thrombosis or previous pulmonary embolism, the recommended dosage is usually one tablet (10 mg) once a day.

Do not exceed the recommended dose.

Duration of treatment
- In a hip replacement operation, the duration of treatment is usually 5 weeks.
- In a knee replacement operation, the duration of treatment is usually 2 weeks.
- To prevent blood clots from re-occurring in the veins of your legs (deep vein thrombosis) and in the blood vessels of your lungs (pulmonary embolism), after completing 6 months of treatment for deep vein thrombosis or previous pulmonary embolism, the duration of treatment will be decided by your doctor.

Method of administration
Swallow the medicine with water.
Taking the medicine at the same time every day will help you remember to take it.
If you have difficulty swallowing the tablet whole, talk to your doctor about other ways to take Rivaroxaban Taro 10 mg. The tablet may be crushed and mixed with water or apple puree immediately before you take it.
If necessary, your doctor will give you crushed Rivaroxaban Taro 10 mg tablet through a stomach tube.
There is no information regarding splitting/chewing the tablet.

If you have accidentally taken a higher dose, contact your doctor immediately. Taking too much Rivaroxaban Taro 10 mg 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, take a dose as soon as you remember. Take the next tablet on the following day and then carry on with normal treatment. Under no circumstances should you take a double dose!

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine before completing treatment without consulting your doctor, because Rivaroxaban Taro 10 mg prevents the development of a dangerous condition.

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

Like all medicines, using Rivaroxaban Taro 10 mg 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 10 mg 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 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 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 system abnormalities and systemic illness (DRESS syndrome). These side effects are very rare (up to 1 in 10,000 users).

Signs of a severe allergic reaction:
- 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
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), nose bleed, bleeding in the gums
- 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
- bleeding following an operation
- oozing of blood or fluid from a 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, 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 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 show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets
- fainting
- feeling 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
- collection of blood (haematoma) in the groin as a complication of the cardiac procedure where a catheter is inserted in your 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
- bleeding in the kidney, which is sometimes accompanied by presence of blood in the urine, leading to inability of the kidneys to work properly (anticoagulant-related nephropathy)
- 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)

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) 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.
- 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, titanium dioxide, macrogol, iron oxide yellow, carmine).

What the medicine looks like and contents of the pack:
round, pink film-coated tablets. One side is imprinted with "□" and the other with "10". The medicine is marketed in a pack containing 30 film-coated tablets.

Registration holder and manufacturer's name and address:
Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

This leaflet was revised in November 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
162-53-35228-00