PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Rivar Teva 10 mg

Film-coated tablets

Each film-coated tablet contains:
Rivaroxaban 10 mg
For information regarding inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Patient safety information card
In addition to the leaflet, the Rivar Teva 10 mg preparation has a patient safety information card. This card contains important information that you must know and act accordingly before starting treatment with Rivar Teva 10 mg and during the treatment.
Please review the patient safety information card and the patient leaflet before starting to use the preparation.
You should keep the leaflet and the card for further review, if necessary.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Rivar Teva 10 mg is intended for:
- Prevention of the formation of blood clots in the veins, in adults after an elective hip or knee replacement surgery.
- Prevention of the recurrence of blood clots in the veins of the legs (deep vein thrombosis) and in the blood vessels of the lungs (pulmonary embolism) in adults, after having completed 6 months of treatment for deep vein thrombosis or for a previous pulmonary embolism.

Therapeutic class: Rivar Teva 10 mg belongs to a class of medicines called anticoagulants, and acts by reducing the tendency to produce blood clots by blocking a factor involved in the clotting process (factor Xa).

2. BEFORE USING THE MEDICINE

Do not use this medicine if:
- You are sensitive (allergic) to rivaroxaban or to any of the other ingredients the medicine contains (for information regarding inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information").
- You suffer from excessive bleeding.
- You have a disease or condition in an organ of the body that increases the risk of serious bleeding (such as: stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes).
- You are taking anticoagulants (such as: warfarin, dabigatran, apixaban or heparin), except for cases of switching from treatment with one anticoagulant to another, or while receiving 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 Rivar Teva 10 mg and inform your doctor if any of the abovementioned conditions apply to you.

Special warnings regarding the use of the medicine
Talk to the doctor or pharmacist before taking Rivar Teva 10 mg.

Special caution is required when using Rivar Teva 10 mg. Before treatment with Rivar Teva 10 mg, inform the doctor:
- If you have an increased risk of bleeding, as could be the case in any of the following situations:
  - Moderate to severe kidney disease, since kidney function may influence the amount of medicine working in your body.
  - You are taking other anticoagulants (e.g. warfarin, dabigatran, apixaban or heparin), when changing from one anticoagulant to another, or while receiving heparin through a venous or arterial line to keep it open (see below in section 2 – "Drug interactions").
  - Bleeding disorders.
  - Very high blood pressure, which is not controlled by medicinal treatment.
  - Diseases of the stomach or bowel that might result in bleeding, such as: inflammation of the stomach or the intestines, or inflammation of the esophagus, e.g. due to gastroesophageal reflux disease (a disease in which stomach acid goes upwards into the esophagus) or tumors located in the stomach or bowels or genitals or urinary tract.
  - Problems with the blood vessels of the retina (retinopathy).
  - A lung disease where the bronchi are enlarged and filled with purulent secretions (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 whether the treatment should be changed.
- If your doctor determines that your blood pressure is unstable or if another treatment or surgical procedure to remove the blood clot from your lungs is planned.

If any of the abovementioned conditions apply to you, tell your doctor before you take the medicine. Your doctor will decide whether you should be treated with Rivar Teva 10 mg and whether you should be kept under close observation.
- If the doctor thinks that you have an increased risk for developing a stomach or intestinal ulcer, he may also prescribe you with a treatment to prevent it.

If you need to undergo surgery
- It is highly important to take Rivar Teva 10 mg before and after the surgery at the exact times your doctor has scheduled for you.
- If your surgery involves an intraspinal catheter or injection (e.g., for epidural or spinal anesthesia or for pain relief):
  - It is highly important to take Rivar Teva 10 mg at the exact times your doctor has scheduled for you.
  - Refer to your treating doctor immediately if you experience numbness or weakness in the legs or intestinal problems or bladder problems after the anesthesia wears off, as this requires urgent medical intervention.

Children and adolescents
The medicine is not intended for use in children and adolescents under the age of 18.
Information regarding the use in children and adolescents is insufficient.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:
- Certain anti-fungal medicines (such as: fluconazole, itraconazole, voriconazole, posaconazole) except for those only intended for topical application.
- Tablets containing ketoconazole for treatment of Cushing's syndrome – a condition in which the body produces an excess of cortisol.
- Certain medicines for the treatment of bacterial infections (such as: clarithromycin, erythromycin).
- Certain anti-viral medicines for treatment of human immunodeficiency virus (HIV) infections/AIDS (such as: ritonavir).
- Other anticoagulants (such as: enoxaparin, clopidogrel or vitamin K antagonists, such as warfarin and acenocoumarol).
- Anti-inflammatory and analgesic medicines (such as: naproxen or acetylsalicylic acid [aspirin]).
- Dronedarone, a medicine for treatment of irregular heartbeat.
- Certain medicines for treatment of depression (selective serotonin reuptake inhibitors [SSRIs] or serotonin-norepinephrine reuptake inhibitors [SNRIs]).

If any of the abovementioned conditions apply to you, tell your doctor before taking the medicine, as these medicines may increase the effect of Rivar Teva 10 mg. Your doctor will decide whether to treat you with Rivar Teva 10 mg and whether close medical supervision is required.

Moreover, the doctor or pharmacist should be informed if you are taking:
- Certain medicines for treatment of epilepsy (such as: phenytoin, carbamazepine, phenobarbital).
- The herbal preparation for treatment of depression St. John's wort (hypericum).
- Rifampicin (an antibiotic).

If any of the abovementioned conditions apply to you, tell your doctor before taking the medicine, as these medicines may decrease the effect of Rivar Teva 10 mg. Your doctor will decide whether to treat you with Rivar Teva 10 mg and whether close medical supervision is required.

Use of the medicine and food
Rivar Teva 10 mg can be taken with or without food.

Pregnancy, breastfeeding and fertility
Do not take Rivar Teva 10 mg if you are pregnant or breastfeeding.
If there is a chance that you might become pregnant, you must use a reliable contraceptive while taking Rivar Teva 10 mg.
If you become pregnant while taking the medicine, inform the treating doctor immediately, who will decide how to continue the treatment.

Driving and operating machinery
Rivar Teva 10 mg may cause dizziness (a common side effect) or fainting (an uncommon side effect) (see section 4 – "Side effects"). Do not drive, ride a bicycle, use tools or operate machinery while using Rivar Teva 10 mg if you experience these symptoms.

Important information about some of the ingredients of the medicine
The medicine contains lactose and sodium.
If you have been told by the doctor that you have an intolerance to certain sugars, speak to the doctor before starting to take Rivar Teva 10 mg.
The medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is thus considered to be "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined only by the doctor.
- To prevent the formation of blood clots in the veins following surgery for hip or knee replacement, the generally accepted dosage is:
  One tablet of Rivar Teva 10 mg once daily.
  Take the first tablet 6-10 hours after the surgery if the doctor decides that your condition is stable. Thereafter take one tablet per day until your doctor instructs you to stop.
- To prevent the recurrence of blood clots in the veins of the legs (deep vein thrombosis) and in pulmonary blood vessels (pulmonary embolism) after having completed 6 months of treatment for deep vein thrombosis or for a previous pulmonary embolism, the generally accepted dosage is:
  One tablet of Rivar Teva 10 mg once daily.

Do not exceed the recommended dose.

Duration of treatment
- In hip joint replacement surgery, the duration of treatment is usually 5 weeks.
- In knee joint replacement surgery, the duration of treatment is usually 2 weeks.
- To prevent the recurrence of blood clots in the veins of the legs (deep vein thrombosis) and in pulmonary blood vessels (pulmonary embolism) after having completed 6 months of treatment for deep vein thrombosis or for a previous pulmonary embolism, the duration of treatment will be determined by the doctor.

How to take the medicine
Swallow the medicine, preferably 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, speak to your doctor about other ways to take Rivar Teva 10 mg. The tablet may be crushed and mixed with water or apple puree immediately before it is taken.
If necessary, your doctor will administer crushed Rivar Teva 10 mg through a feeding tube into your stomach.
No information is available regarding halving/chewing.

If you accidentally take a higher dosage you should refer to your treating doctor immediately. Taking too much Rivar Teva 10 mg increases your risk for bleeding.
If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of a hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. Take the next tablet on the following day and continue with the treatment as usual. Never take a double dose!
Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop the treatment with the medicine before having completed the treatment without consulting the doctor, as Rivar Teva 10 mg prevents the development of a dangerous condition.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Rivar Teva 10 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Like other similar medicines for reducing the formation of blood clots, Rivar Teva 10 mg may cause potentially life-threatening bleeding. Heavy bleeding may cause a sudden drop in blood pressure (shock).In certain cases the bleeding may be occult.

Refer to the doctor immediately if you experience any of the following side effects:

Signs of bleeding:
- Bleeding in the brain or inside the skull (symptoms may include headache, one-sided weakness, vomiting, convulsions, decreased level of consciousness and neck stiffness. This is a serious medical emergency, you should seek immediate medical attention!).
- Prolonged or heavy bleeding.
- Abnormal weakness, tiredness, pallor, dizziness, headache, unexplained swelling, shortness of breath, chest pain or angina pectoris.

Your doctor will decide whether to keep you under close observation or change the treatment.

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).

The frequency of these side effects is 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.

The frequencies of severe allergic reactions are very rare (anaphylactic reactions, including anaphylactic shock; may affect up to 1 in 10,000 users) or uncommon (angioedema and allergic edema; may affect up to 1 in 100 users).

Additional side effects

Common side effects (effects that may affect up to one in 10 users):
- Reduction in red blood cells which can cause pallor, weakness or breathlessness
- Gastric or intestinal bleeding, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nose bleeding, bleeding in the gums
- Bleeding into the eye (including bleeding from the whites of the eyes)
- Bleeding into a body tissue or cavity (local hematoma, bruising)
- Coughing blood
- Bleeding from the skin or under the skin
- Post-operative bleeding
- Oozing of blood or fluid from a surgical wound
- Limb swelling
- Pain in the limbs
- Impaired function of the kidneys (may be seen in tests performed by your doctor)
- Fever
- Abdominal pain, digestive difficulties, nausea or vomiting, constipation, diarrhea
- Low blood pressure (symptoms may be feeling dizzy or fainting when standing up)
- General decrease in strength and energy (weakness, tiredness), headache, dizziness
- Rash, itching of the skin
- Blood tests may show an increase in some liver enzymes

Uncommon side effects (effects that may affect up to one 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 platelets, which are cells that help blood to clot)
- Allergic reactions, including allergic skin reactions
- Impaired liver function (can be discovered in tests performed by the doctor)
- Blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets
- Fainting
- General malaise
- Rapid heartbeat
- Dry mouth
- Hives (urticaria)

Rare side effects (effects that may affect up to one in 1,000 users):
- Bleeding into a muscle
- Cholestasis (decreased bile flow), inflammation of the liver (hepatitis), including hepatocellular injury (inflamed liver, including liver injury)
- Yellowing of the skin and the eyes (jaundice)
- Localized swelling
- Local internal hematoma in the groin as a complication of the cardiac procedure where a catheter is inserted into your leg artery

Very rare side effects (effects that may affect up to one in 10,000 users):
- Accumulation of eosinophils, a type of granulocyte white blood cells that cause lung inflammation (eosinophilic pneumonia)

Side effects with unknown frequency (frequency cannot be estimated from the available data):
- Kidney failure after a severe bleeding
- Bleeding in the kidney, sometimes with the presence of blood in the urine that leads to inability of the kidneys to function 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 a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il.

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place below 25°C.**
- **Crushed tablets**
  Crushed tablets are stable in water or apple puree for up to 4 hours.

Do not discard medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:
Lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulfate, polyvinyl alcohol (part. hydrolyzed), titanium dioxide, magnesium stearate, macrogol, talc, carmine, iron oxide yellow, iron oxide red.

What does the medicine look like and what are the contents of the package:
A round, pink, film-coated tablet, debossed with "T" on one side of the tablet and with "1R" on the other side.
The tablets come in blister packs in packages of 28, 30, 56 or 60 tablets.
Not all package sizes may be marketed.

Name and address of the license holder and manufacturer:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in January 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health:
168-08-36158

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