(PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

# Rivar Teva 15 mg Film-coated tablets

Each film-coated tablet contains: Rivaroxaban 15 mg

### Rivar Teva 20 mg

Film-coated tablets Each film-coated tablet contains: Rivaroxaban 20 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 preparation has a patient safety information card. This card contains important safety information that you must know and act accordingly before starting treatment with Rivar Teva 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

Rivar Teva 15 mg and Rivar Teva 20 mg are intended for adults in the following situations:

• Prevention of blood clots in the brain (stroke) and other blood vessels in the body, in patients with irregular heartbeat called non-valvular atrial fibrillation, who have one or more of the following risk factors: heart failure, hypertension, age (75 or older), diabetes, prior stroke or transient ischemic attack ischemic attack

Treatment of blood clots in the veins of the legs (deep vein thrombosis, DVT) and in the blood vessels of the lungs (pulmonary embolism, PE), and prevention of the recurrence of blood clots in the veins of the legs

and/or lungs.

Rivar Teva 15 mg and Rivar Teva 20 mg are intended for children and adolescents under the age of 18 who weigh 30 kg or more in the following situation:

• Treatment of blood clots and prevention of the recurrence of blood clots in the veins or blood

vessels of the lungs, after an initial treatment of at least 5 days with medicines for injection used for treatment of blood clots.

Therapeutic class: Rivar Teva 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") 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 (e.g. warfarin, dabigatran, apixaban or heparin), except when changing from 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 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. Special caution is required when using Riva

Teva. Before treatment with Rivar Teva, tell the If you have an increased risk of bleeding, as could be the case in any of the following

- situations: 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 should you use the medicine?" regarding disease). 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 bowels or stomach, 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 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 If you need to undergo surgery or an invasive

## It is highly important to take Rivar Teva before

- and after the surgery or invasive procedure at the exact times your doctor has scheduled for 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 before and
- after the injection or the removal of the catheter 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

Rivar Teva tablets are not recommended for children who weigh less than 30 kg. Information regarding the use in children and adolescents for the indications intended for adults 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 fluconazole, itraconazole, voricona 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]).
any of the abovementioned conditions

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. Your doctor will decide whether to treat you with Rivar Teva 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

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. Your doctor will decide whether to treat you with Rivar Teva and whether close medical supervision is required.
 Use of the medicine and food
 The medicine must be taken with food and it is

The medicine must be taken with food and it is recommended to swallow the tablet with water.

Pregnancy, breastfeeding and fertility
Do not take Rivar Teva 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.

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 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 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.

The medicine contains less than 1 mmol of sodium

(23 mg) per tablet, and is thus considered to be 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.

Adults
To prevent blood clots in the brain (stroke) and in other blood vessels in your body, the generally accepted dosage is one tablet of Rivar Teva

20 mg once a day.

If you have kidney impairment, the dosage may be reduced to one tablet of Rivar Teva 15 mg

once a day.

If you need to undergo a procedure to treat blocked blood vessels in your heart (a procedure called a percutaneous coronary intervention PCI with an insertion of a stent), there is limited information about reducing the dosage to one tablet of Rivar Teva 15 mg once a day, in addition to an antiplatelet medicine, such as clopidogrel.

To treat blood clots in the veins of your legs and in the blood vessels of your lungs, and to prevent blood clots from reoccurring, the generally accepted dosage is one tablet of Rivar generally accepted dosage is one tablet of Rivar Teva 15 mg twice a day for the first 3 weeks, and then one tablet of Rivar Teva 20 mg once a day. After completing at least 6 months of treatment, your doctor may decide to continue treatment with Rivar Teva 10 mg, one tablet a day. If you have kidney impairment and take Rivar Teva 20 mg once a day, your doctor may decide to reduce the dosage after 3 weeks to one tablet of Rivar Teva 15 mg once a day, if the risk for bleeding is higher than the risk of another blood clot forming.

clot forming

Children and adolescents

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

The recommended dosage for children and adolescents who weigh between 30 kg and less than 50 kg is one tablet of Rivar Teva 15 mg once daily

15 mg once daily.

The recommended dosage for children and adolescents who weigh 50 kg or more is one tablet of Rivar Teva 20 mg once daily.

Take the dose of Rivar Teva with a beverage

should be taken every day at the same time. Consider using an alarm clock to remind you. For parents or caregivers: please observe the child while taking the medicine to ensure that the whole dose is taken.

Since the dosage of Rivar Teva is based on body weight, it is important to schedule regular appointments with the doctor, as it may necessary to adjust the dosage as the body weight changes

Never adjust the dosage of Rivar Teva by yourself. The doctor will adjust the dosage if Do not halve the tablet in an attempt to give part

of the tablet dose. If a lower dosage is required, use a dosage form of rivaroxaban granules for preparation of oral suspension. Use the dosage form of rivaroxaban granules for preparation of oral suspension for children and adolescents who are unable to swallow the tablets whole.

If the dosage form of granules for preparation of oral suspension is not available, the tablet may be crushed and mixed with water or apple puree immediately before it is taken. You should eat immediately after taking the crushed medicine. If necessary, your doctor may administer a crushed tablet of Rivar Teva through a feeding tube into your stomach.

Do not exceed the recommended dose.

## **Duration of treatment**

Rivar Teva should be taken every day until the

doctor instructs you to stop.

The doctor will decide about the duration of

treatment with the medicine. How to take the medicine

Rivar Teva

The medicine must be taken with food and it is recommended to swallow the tablet with water. If you have difficulty swallowing the tablet whole speak to your doctor about other ways to take

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

If necessary, your doctor may administer a crushed tablet of Rivar Teva through a feeding tube into your stomach No information is available regarding halving/

chewing.

Taking the medicine at the same time every day If you spit out the dose or vomit

If less than 30 minutes have passed after taking

Rivar Teva, take a new dose.

If more than 30 minutes have passed after taking taking Rivar Teva, do not take a new dose. In

this case, take the next dose of Rivar Teva at the next scheduled time.

Refer to the doctor if you repeatedly spit out the dose or vomit after taking Rivar Teva

If you accidentally take a higher dosage you should refer to your treating doctor immediately. Taking too much Rivar Teva 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. forget to take this medicine at the required time Adults, children and adolescents

# If your dosage is one tablet of Rivar Teva 15 mg or Rivar Teva 20 mg 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 on the following day and then once a day as usual, and consult your doctor. Adults If your dosage is one tablet of Rivar Teva

15 mg **twice** a day, take a dose as soon as you remember. Do not take more than two tablets of Rivar Teva 15 mg in one day. You can take two tablets of Rivar Teva 15 mg together to make a dose of 30 mg for one day. On the following day

continue taking one tablet of Rivar Teva 15 mg twice a day. 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 without consulting the doctor, since Rivar Teva treats and prevents serious conditions.

If you stop taking the medicine you compromise

is therapeutic and preventive capacity.

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.

As with any medicine, using Rivar Teva 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 may cause potentially life-threatening bleeding. Heavy bleeding may cause a sudden drop in blood pressure (shock). In certain cases the bleeding

4. SIDE EFFECTS

may be occult. Refer to the doctor immediately if you or the

child experiences 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, 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 severe skin reactions:

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

The frequency of these side effects is very rare (up to 1 in 10,000 users).

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.

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 reported in adults, children and adolescents

Common side effects (effects that may affect

Gastric or intestinal bleeding, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nose bleeding, bleeding in

the gums

tests performed by your doctor) Feve

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

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

Hives (urticaria) Rare side effects (effects that may affect up to 1 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)

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 1 in 10,000 users):

inflammation (eosinophilic pneumonia)
Side effects with unknown frequency
(frequency cannot be estimated from the
available data):

bleeding) Side effects in children and adolescents

children and adolescents:

Nose bleeding

- Vomiting
Common side effects (effects that may affect Increased heartbeat

Thrombocytopenia (low number of platelets, which are cells that help blood to clot)

Heavy menstrual bleeding
 Uncommon side effects (effects that may affect

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

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

(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

household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

Rivar Teva 15 mg: Lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulfate, polyvinyl alcohol (part. hydrolyzed), magnesium stearate,

Lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulfate, polyvinyl alcohol (part. hydrolyzed), magnesium stearate, iron oxide red, macrogol, talc.

What does the medicine look like and what are

macrogol, titanium dioxide, talc, iron oxide yellow,

the contents of the package? Rivar Teva 15 mg: a round, orange, film-coated tablet, debossed with "T" on one side of the tablet

The tablets come in blister packs in packages of 28, 30, 56 or 60 tablets.

manufacturer Teva Israel Ltd. 124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in January 2024. Registration numbers of the medicines in the national drug registry of the Ministry of Health: Rivar Teva 15 mg: 168.09.36159 Rivar Teva 20 mg: 168.10.36160

teva

syndrome).

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

Reduction in red blood cells which can cause pallor, weakness or breathlessness

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

Abdominal pain, digestive difficulties, nausea or vomiting, constipation, diarrhea
Low blood pressure (symptoms may be feeling dizzy or fainting when standing up)

Uncommon side effects (effects that 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 platelets, which are cells that help blood to clot)
Allergic reactions, including allergic skin reactions

Dry mouth

Yellowing of the skin and the eyes (jaundice) Localized swelling

Accumulation of eosinophils, a type of granulocyte white blood cells that cause lung

vailable 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)

and adolescents treated with rivaroxaban were similar to those observed in adults and were mostly mild to moderate in their severity. Side effects that were observed more often in

Very common side effects (effects that may affect more than 1 in 10 users): Headache Fever

up to 1 in 10 users): Blood tests may show an increase in bilirubin (bile pigment)

up to 1 in 100 users):
Blood tests may show an increase in a certain type of bilirubin (direct bilirubin, bile pigment)

an explicit instruction from the doctor.

Do not use the medicine after the expiry date

Crushed tablets are stable in water or apple puree for up to 4 hours.

Do not discard medicines via wastewater or

6. ADDITIONAL INFORMATION In addition to the active ingredient, the medicine also contains:

iron oxide red Rivar Teva 20 mg:

and with "3R" on the other side.

Rivar Teva 20 mg: a round, red, film-coated tablet, debossed with "T" on one side of the tablet and with "7R" on the other side.

Not all package sizes may be marketed.

Name and address of the license holder and

Rivar 15 mg 20 mg PIL MW0124