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

This medicine is dispensed with a doctor's prescription only

Ticata 90 mg

Coated Tablets

Composition:
Each tablet contains:
Ticagrelor 90 mg

Ticata 60 mg

Coated Tablets

Composition:
Each tablet contains:
Ticagrelor 60 mg

For a list of inactive and allergenic ingredients in the preparation, please see section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ticata, co-administered with acetylsalicylic acid (aspirin), is indicated for the prevention of atherothrombotic events in adult patients with:
- acute coronary syndromes or
- a history of myocardial infarction and a high risk of developing an atherothrombotic event.

Limitations of use: 90 mg twice daily during the first year after an acute coronary syndrome event followed by 60 mg twice daily for an additional two years.

Therapeutic group:

Platelet aggregation inhibitor.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you are allergic to the active substance ticagrelor or to any of the other ingredients of the medicine (please see section 6 "Further information").
- you are currently suffering from bleeding.
- you have a history of stroke caused by intracerebral bleeding.
- you are suffering from a severe liver disease.
- you are taking any of the following medicines: ketoconazole (for treatment of fungal infections), clarithromycin (for treatment of bacterial infections), nefazodone (antidepressant), ritonavir and atazanavir (for treatment of HIV infections and AIDS), as co-administration may increase the level of **Ticata** in the blood.

Special warnings regarding use of the medicine

Before treatment with Ticata, tell the doctor if:

- you are at increased risk of bleeding due to:
  - Recent severe injury.
  - Recent surgery (including dental work; ask your dentist about this).
  - Condition that affects blood clotting.
  - Recent bleeding in the stomach or intestine (such as a stomach ulcer or polyps in the colon).
- you are due to undergo surgery (including dental work) during the course of treatment with **Ticata**. Due to an increased risk of bleeding, the doctor may instruct you to stop taking **Ticata** 5 days before the planned surgery.
- you have a slower heart rate than normal (generally less than 60 beats per minute) and you do not have a pacemaker.
- you are suffering from asthma or a lung disease or breathing difficulties.
- you develop irregular breathing patterns such as: speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.
- you have had liver problems or have suffered in the past from a disease which may affect your liver.
- blood tests showing that you are suffering from a high level of uric acid in the blood.

If any of the above apply to you (or if you are not sure), talk to the doctor or pharmacist before taking the medicine.

If you are taking **Ticata** and heparin:

- The doctor may refer you for a blood test to check for a rare platelet disorder caused by heparin if he suspects it. It is important that you inform the doctor that you are taking both **Ticata** and heparin, as **Ticata** may affect the diagnostic test.

Children and adolescents

Ticata is not recommended for children and adolescents under 18 years of age.

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you are taking:

- rosuvastatin (a medicine for treatment of high cholesterol)
- simvastatin or lovastatin (medicines for treatment of high cholesterol) at a dose of more than 40 mg per day
- rifampicin (antibiotic)
- phenytoin, carbamazepine and phenobarbital (for treatment of convulsions)
- digoxin (for treatment of heart failure)
- cyclosporine (immunosuppressant)
- quinidine and diltiazem (for treatment of heart rhythm disorders)
- beta blockers and verapamil (for treatment of hypertension)
- morphine and other opioids (for treatment of severe pain)

Especially if you are taking medicines from the following groups that may increase the risk of bleeding:

- Oral anticoagulants (blood thinners) including warfarin.
- Non-steroidal anti-inflammatory drugs (NSAIDs), often taken as painkillers, such as ibuprofen and naproxen.
- Antidepressants from the SSRI (selective serotonin reuptake inhibitor) family, such as paroxetine, sertraline and citalopram.
- Other medicines such as ketoconazole (for treatment of fungal infections); clarithromycin (for treatment of bacterial infections); nefazodone (for treatment of depression); ritonavir and atazanavir (for treatment of HIV infections and AIDS); cisapride (for treatment of heartburn); ergotamines (for treatment of migraine and headaches).

Tell the doctor that because you are taking **Ticata**, you may have an increased risk of bleeding if the doctor gives you fibrinolytics, such as streptokinase or alteplase.

Use of the medicine and food

The tablet can be taken with or without food.

Pregnancy and breastfeeding

- It is not recommended to use **Ticata** if you are pregnant or may become pregnant. Women of childbearing age taking **Ticata** should use appropriate contraceptive measures to prevent pregnancy.
- Consult the doctor before taking the medicine if you are breastfeeding. The doctor will discuss with you the benefits and risks of taking **Ticata** while breastfeeding.

Driving and use of machinery

Ticata is not likely to affect your ability to drive or use machines. If you feel dizzy or confused while taking **Ticata**, use caution while driving or using machines.

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 not sure regarding the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

Ticata 90 mg:

- The starting dosage is two tablets at the same time (loading dose of 180 mg). This dose is usually given in the hospital.
- After the starting dosage, the usual dosage is one 90 mg tablet, twice a day, for up to 12 months, unless instructed otherwise by the doctor.

Ticata 60 mg:

- The usual dose is one tablet of 60 mg, twice a day. Continue taking **Ticata 60 mg** as long as the doctor tells you and up to two years.

Do not exceed the recommended dose.

Taking Ticata with other medicines to prevent blood clots:

Usually, the doctor will instruct you also to take acetylsalicylic acid. It is a substance found in many medicines which is used to prevent the formation of blood clots. The doctor will tell you how much to take (the dose will usually be 75-150 mg per day).

Manner of treatment:

- The tablet can be taken with or without food.
- Take the tablet at set times in the day (e.g., one tablet in the morning and one tablet in the evening).
- If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.

If you are in the hospital, you may be given this tablet mixed with some water and given through a tube via the nose (nasogastric tube).

If you have accidentally taken a higher dosage: An overdose can cause increased risk of bleeding. If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, refer to a doctor immediately or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine: If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor.

If you stop taking the medicine: Do not stop the treatment with **Ticata** without consulting the doctor. Take the medicine on a regular basis and for as long as the doctor keeps prescribing it. Discontinuation of **Ticata** treatment may increase your risk of another heart attack, stroke or death from a disease associated with the heart or blood vessels.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult with the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Ticata** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Ticata affects blood clotting, so most side effects are related to bleeding. Bleeding may occur in any part of the body. Some bleeding is common (like bruising and nosebleeds).

Severe bleeding is uncommon, but can be life-threatening.

<u>Effects that require special attention</u>:

<u>Refer to the doctor immediately if the following effects occur; you may need urgent medical treatment</u>:

Bleeding into the brain or inside the skull is an uncommon side effect, and may cause signs of a stroke such as:

- Sudden numbness or weakness of the arm, leg or face, particularly on one side of the body.
- Sudden confusion, difficulty speaking or understanding others.
- Sudden difficulty walking or loss of balance or co-ordination.
- Sudden dizziness or sudden severe headache without a known reason.

Signs of bleeding such as:

- Severe bleeding or bleeding that cannot be controlled.
- Unexpected bleeding or bleeding that lasts a long time.
- Pink, red or brown urine.
- Bloody vomit or your vomit looks like coffee grounds.
- Black or bloody stools (look like tar).
- Coughing up or vomiting blood clots.

Fainting (syncope):

- A temporary loss of consciousness due to a sudden drop in blood flow to the brain (common).

Signs of a blood clotting problem called "Thrombotic Thrombocytopenic Purpura" (TTP), such as:

- Fever and purplish spots (purpura) on the skin or in the mouth, with or without yellowing of the skin or eyes (jaundice), unexplained extreme tiredness or confusion.

Consult a doctor if the following effects occur:

- **Shortness of breath – this is very common.** This effect may be due to your heart disease or another cause, or it might be a side effect of **Ticata**. **Ticata**-related breathlessness is generally mild and characterized as a sudden, unexpected hunger for air usually occurring at rest, may appear in the first weeks of treatment and in many cases may disappear. If the shortness of breath gets worse with time or lasts a long time, tell the attending doctor, who will decide if treatment or further investigation is necessary.

Additional side effects:

Very common side effects (effects that occur in more than one user in ten):

- High level of uric acid in the blood (as observed in tests)
- Bleeding caused by blood disorders

Common side effects (effects that occur in 1-10 users in 100):

- Bruises
- Headache
- Dizziness or a feeling like the room is spinning
- Diarrhea or digestive disturbances
- Nausea
- Constipation
- Rash
- Stinging and itching
- Severe pain and swelling in your joints – these are signs of gout
- Feeling dizzy or lightheaded, or having blurred vision – these are signs of low blood pressure

- Nosebleed
- Bleeding more than is normal after surgery or from cuts (for example, while shaving) and wounds
- Bleeding from the stomach lining (ulcer)
- Bleeding gums

Uncommon side effects (effects that occur in 1-10 users in 1,000):
- Allergic reaction – rash, itching or a swollen face or swollen lips/tongue may be signs of hypersensitivity/an allergic reaction
- Confusion
- Visual problems caused by blood in the eye
- Vaginal bleeding not during the monthly menstruation or heavier than usual
- Bleeding into the joints and muscles causing painful swelling
- Blood in the ear
- Internal bleeding that causes dizziness or lightheadedness

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- Abnormally low heart rate (usually lower than 60 beats per minute)

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment", found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il
Additionally, you can report to "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?

- 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 explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C and in a place protected from light.

6. FURTHER INFORMATION

Ticata 90 mg:

In addition to the active ingredient, the medicine also contains:
Mannitol, Calcium hydrogen phosphate dihydrate, Hydroxypropyl cellulose, Crospovidone, Magnesium stearate, Coating blend (white).

What the medicine looks like and contents of the pack:
Round, biconvex, white, coated tablets with a break line on one side.
The package contains 14, 56, 60, 100 or 168 tablets.
Not all pack sizes may be marketed.

Ticata 60 mg:

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

Mannitol, Calcium hydrogen phosphate dihydrate, Hydroxypropyl cellulose, Crospovidone, Magnesium stearate, Yellow coating blend.

What the medicine looks like and contents of the pack:
Round, biconvex, mustard-colored, coated tablets with a break line on one side.
The package contains 14, 56, 60 or 168 tablets.
Not all pack sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park**.**

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Ticata 90 mg: 176-96-37289-99
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