

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

This medicine is dispensed with a doctor's prescription only

**Ticagrelor Taro 60 mg
Film-coated tablets**

Active ingredient

Each tablet contains
ticagrelor 60 mg

**Ticagrelor Taro 90 mg
Film-coated tablets**

Active ingredient

Each tablet contains
ticagrelor 90 mg

Inactive ingredients and allergens in this 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.

1. What is this medicine intended for?

Ticagrelor Taro, co-administered with acetylsalicylic acid (aspirin), is intended for the prevention of atherothrombotic events in adult patients with:

- Acute coronary syndromes
- A history of myocardial infarction and a high risk of developing an atherothrombotic event.

Limitations of use:

A dosage of 90 mg twice daily during the first year after an acute coronary syndrome event followed by a dosage of 60 mg twice daily for additional 2 years.

Therapeutic group:

Platelet aggregation inhibitor.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient ticagrelor or to any of the other ingredients in this medicine (see section 6 'Additional information').
- you are currently suffering from bleeding.
- you have a history of stroke caused by intracerebral bleeding.
- you have 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), since concomitant use may increase the level of Ticagrelor Taro in the blood.

Special warnings about using this medicine

Before using Ticagrelor Taro, tell your 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 colon polyps).

- you are due to undergo surgery (including dental work) during treatment with Ticagrelor Taro. Due to an increased risk of bleeding, the doctor may instruct you to stop taking Ticagrelor Taro 5 days before the planned surgery.
- you have a slower than normal heart rate (generally below 60 beats per minute) and you do not have a pacemaker.
- you are suffering from asthma or a lung disease or difficulty breathing.
- 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 have affected your liver.
- blood tests show that you are suffering from a high level of uric acid in the blood.

If any of the conditions listed above applies to you (or you are not sure), consult your doctor or pharmacist before taking the medicine.

If you are taking Ticagrelor Taro and heparin:

- Your doctor may refer you for a blood test to diagnose a rare platelet problem caused by heparin if your doctor suspects you have the disease. It is important to inform your doctor that you are taking both Ticagrelor Taro and heparin, as Ticagrelor Taro may affect the diagnostic test.

Children and adolescents

Ticagrelor Taro is not recommended for children and adolescents under the age of 18.

Drug interactions

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:

- rosuvastatin (a medicine for treatment of high cholesterol)
- simvastatin or lovastatin (medicines for treatment of high cholesterol) at dosages of higher 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 rhythm disorders)
- beta blockers and verapamil (for treatment of hypertension)
- morphine and other opioids (used to treat 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 pain killers, such as ibuprofen and naproxen.
- Antidepressants from the SSRI (selective serotonin reuptake inhibitors) class 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 - human immunodeficiency virus - infections and AIDS - acquired immunodeficiency syndrome); cisapride (for treatment of heartburn); ergotamines (for treatment of migraine and headaches).

Also tell your doctor that because you are taking Ticagrelor Taro, you may have an increased risk of bleeding if the doctor gives you fibrinolytics (clot dissolvers) such as streptokinase or alteplase.

Using this medicine and food

The tablet may be taken with or without food.

Pregnancy and breastfeeding

- Ticagrelor Taro is not recommended for use if you are pregnant or may become pregnant. Women of childbearing age taking Ticagrelor Taro must use appropriate contraception.
- Consult a doctor before using this medicine if you are breastfeeding. Your doctor will discuss with you the benefit and risk of taking Ticagrelor Taro while breastfeeding.

Driving and using machines

Ticagrelor Taro should not have any effect on your ability to drive or use machines. If you feel dizzy or confused while taking Ticagrelor Taro, use caution when driving or using machines.

Important information about some of this medicine's ingredients

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

The tablets contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor for advice before taking this medicine.

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.

The recommended dose is usually:

Ticagrelor Taro 90 mg:

- The starting dosage is 2 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 a period of up to 12 months, unless your doctor instructs you otherwise.

Ticagrelor Taro 60 mg:

- The usual dose is one tablet of 60 mg, twice a day. Continue taking Ticagrelor Taro 60 mg as long as your doctor tells you and for a period of up to two years.

Do not exceed the recommended dose.

Taking Ticagrelor Taro with other anticoagulants

Your doctor will usually instruct you to also take acetylsalicylic acid. This is a substance found in many medicines that are used to prevent the formation of blood clots. Your doctor will instruct you on how much to take (the dosage is usually 75-150 mg daily).

Form of administration

- The tablet may be taken with or without food.
- Swallow the tablet whole.
- Take the tablet at set times in the day (e.g., one tablet in the morning and one tablet in the evening).
- If you have trouble swallowing the tablet - you can crush the tablet and mix it with water as follows:
 - Crush the tablet to a fine powder

- Pour the powder into half a glass of water, stir and drink immediately
- To make sure there is no medicine left in the glass, add another half a glass of water to the empty glass and drink the water.

If you are hospitalized, you may receive this tablet mixed in a small amount of water through a nasogastric tube.

If you have accidentally taken a higher dose

An overdose can cause increased 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

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Do not stop treatment with Ticagrelor Taro without consulting your doctor. Make sure to take the medicine regularly for as long as your doctor continues to prescribe it. Discontinuation of treatment with Ticagrelor Taro 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 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 Ticagrelor 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.

Ticagrelor Taro 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.

Effects that require special attention

Contact the doctor immediately if the following effects occur. Emergency medical care may be required:

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:

- bleeding that is severe 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 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 (called purpura) on the skin or in the mouth, with or without yellowing of the skin or eyes (jaundice), unexplained extreme confusion or tiredness.

Consult a doctor if the following effects occur:

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

Additional side effects

Very common side effects (effects that appear in more than one in ten users):

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

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

- 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 light-headed, or having blurred vision – these are signs of low blood pressure
- Nosebleed
- Heavier bleeding after surgery or from cuts (for example after shaving) or wounds
- Bleeding from your stomach bleeding (ulcer)
- Bleeding gums

Uncommon side effects (affect 1-10 in 1,000 users):

- Allergic reaction – rash, itching or swelling of the face or lips/tongue may be signs of a hypersensitivity reaction - allergy.
- Confusion
- Visual disturbance caused by blood in your eye
- Vaginal bleeding not during your monthly period or heavier than usual
- Bleeding into your joints and muscles causing painful swelling
- Blood in your ear
- Internal bleeding that causes dizziness or light-headedness

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

- Abnormally low heart rate (usually lower than 60 beats per minute)

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.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or 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 your 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 below 25°C.

6. Additional information

Ticagrelor Taro 60 mg:

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

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate.

Tablet coating:

Hypromellose, titanium dioxide, PEG 400, talc, iron oxide red, iron oxide black.

What the medicine looks like and contents of the pack:

A film-coated, round, pink tablet, with "TT6" imprinted on one side.

The medicine comes in a package containing 14, 28, 30, 42, 56 or 60 tablets packaged in a blister or in a bottle containing 60 tablets.

Not all pack sizes may be marketed.

Ticagrelor Taro 90 mg:

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

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate.

Tablet coating:

Hypromellose, titanium dioxide, Iron oxide yellow, PEG 400, talc.

What the medicine looks like and contents of the pack:

A film-coated, round, yellow tablet, with "TT" imprinted on one side.

The medicine comes in a package containing 14, 28, 30, 42, 56 or 60 tablets packaged in a blister or in a bottle containing 60 tablets.

Not all pack sizes may be marketed.

Manufacturer and registration holder:

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

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

Ticagrelor Taro 60 mg: 176-16-37129-99

Ticagrelor Taro 90 mg: 176-17-37130-99

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For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:



Ticagrelor Taro 90 mg



Ticagrelor Taro 60 mg

<https://israeldrugs.health.gov.il/#!/medDetails/176%2016%2037129%2099>

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For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.