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

This medicine is dispensed with a doctor's prescription only

Ticagrelor Propharm 90 mg
Film-coated Tablets

Active ingredient
Each tablet contains:
ticagrelor 90 mg

Ticagrelor Propharm 60 mg
Film-coated Tablets

Active ingredient
Each tablet contains:
ticagrelor 60 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 using this medicine.

This leaflet contains concise information about this medicine. If you have 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 Propharm, co-administered with acetylsalicylic acid (aspirin), is intended for the prevention of atherothrombotic events in adult patients with

- acute coronary syndrome or
- a history of myocardial infarction and a high risk of developing an atherothrombotic event

Limitations of use:
90 mg dose twice daily during the first year after an event followed by 60 mg dose twice daily for additional 2 years.

Therapeutic group:
Antiplatelets.

2. BEFORE USING THIS MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient ticagrelor or to any of the other ingredients in this medicine (see section 6).
- you are currently suffering from bleeding.
- You have a history of stroke caused by bleeding in the brain.
- you are suffering from a severe liver disease.
- you are taking any of the following medicines: ketoconazole (used to treat fungal infections), clarithromycin (for treatment of bacterial infections), nefazodone (antidepressant), ritonavir and atazanavir (for treatment of HIV infections and AIDS), as concurrent use may increase the level of Ticagrelor Propharm in the blood.

Special warnings about using this medicine
Before using Ticagrelor Propharm, 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).
  - A 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 Propharm. Due to an increased risk of bleeding, the doctor may instruct you to stop taking Ticagrelor Propharm 5 days before the scheduled surgery.
- you have a slower than usual heart rate (usually 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 affect your liver.
- your blood tests show that you are suffering from high levels of uric acid in the blood.

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

If you are taking both Ticagrelor Propharm and heparin:
Your doctor may refer you for diagnostic blood tests if they suspect a rare platelet disorder caused by heparin. It is important that you inform your doctor that you are taking both Ticagrelor Propharm and heparin, as Ticagrelor Propharm may affect the diagnostic test results.

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

Interactions with other medicines
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 to treat high cholesterol)
- simvastatin or lovastatin (medicines for treatment of high cholesterol) at doses 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 heart 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) group, 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 your doctor that since you are taking Ticagrelor Propharm, there may be 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 can be taken with or without food.

Pregnancy and breastfeeding
- Ticagrelor Propharm is not recommended for use if you are pregnant or may become pregnant. Women of childbearing age taking Ticagrelor Propharm must use appropriate measures to prevent pregnancy.
- Consult a doctor before using this medicine if you are breastfeeding. Your doctor will discuss with you the benefits and risks of taking Ticagrelor Propharm while breastfeeding.

Driving and using machines
Ticagrelor Propharm is not likely to affect your ability to drive or use machines. If you feel dizzy or confused while taking Ticagrelor Propharm, be careful while 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'.

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 dosage is usually:
Ticagrelor Propharm 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 up to 12 months unless your doctor orders otherwise.

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

Do not exceed the recommended dose.

Taking Ticagrelor Propharm with other anticoagulants:
Your doctor will generally also instruct you to take acetylsalicylic acid. It is a substance found in many medicines that are used to prevent the development of blood clots. The doctor will instruct you on how much to take (the dosage is generally 75–150 mg daily).

How to take this medicine:
- The tablet can 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, rinse the empty glass with another half a glass of water and drink it.

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

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 forgot 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 Propharm without consulting your doctor. Make sure to take the medicine regularly as long as your doctor continues to prescribe it. Stopping treatment with Ticagrelor Propharm 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 every time you take medicine. Wear glasses if you need them.
If you have further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, using Ticagrelor Propharm may cause side effects in some users. Do not be alarmed by the list of side effects. You may not experience any of them.

Ticagrelor Propharm 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.

Side effects that require special attention

Consult your doctor immediately if the following effects occur. You may need urgent medical attention:
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 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 tiredness or confusion.

Consult a doctor if the following effects occur:
- **Feeling short of breath - this is very common.** It might be due to your heart disease or another cause, or it might be a side effect of Ticagrelor Propharm. Ticagrelor Propharm-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 for many 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 (affect 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
- Bleeding after surgery or from cuts (for example while shaving) and wounds more than is normal
- Bleeding from your stomach lining (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 hypersensitivity reaction- allergy
- Confusion
- Visual problems caused by blood in your eye
- Vaginal bleeding that is heavier, or happens at different times, than your normal period (menstrual) bleeding
- 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) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:
- Store below 25°C.

6. ADDITIONAL INFORMATION
Ticagrelor Propharm 90 mg:

In addition to the active ingredient, this medicine also contains:
Mannitol, calcium hydrogen phosphate dihydrate, sodium starch glycolate, hypromellose, magnesium stearate, Opadry 03B220076 yellow (consists of Hypromellose, titanium dioxide, macrogol, iron oxide yellow, talc).

What the medicine looks like and contents of the pack:
The tablet is film-coated, round, biconvex, yellow, with "90" imprinted on one side.
The package contains 14, 30, 56, 60, 100, 168 or 180 tablets.
Not all pack sizes may be marketed.

Ticagrelor Propharm 60 mg:
In addition to the active ingredient, the medicine also contains:
Mannitol, calcium hydrogen phosphate dihydrate, sodium starch glycolate, hypromellose, magnesium stearate, Opadry 03B240065 pink (consists of hypromellose, titanium dioxide, macrogol, iron oxide red, iron oxide black).

What the medicine looks like and contents of the pack:
The tablet is film-coated, round, biconvex, pink, with "60" imprinted on one side.
The package contains 14, 30, 56, 60, 100 or 168 tablets.
Not all pack sizes may be marketed.

Registration holder and importer's name and address:
Propharm Ltd., POB 4046, 23 Ben Gurion, Zichron Yaacov

Manufacturer's name and address:
Adalvo Limited, Malta, Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, SAN Gwann Industrial Estate, San Gwann, SGN 3000, Malta

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Registration numbers of the medicine in the Ministry of Health's National Drug Registry:
Ticagrelor Propharm 90 mg: 174-17-36869-99
Ticagrelor Propharm 60 mg: 174-16-36868-99