

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

The medicine is dispensed with a doctor's prescription only

Clopidogrel Teva

Tablets

Composition:

Each tablet contains: Clopidogrel (as bisulfate) 75 mg
For information regarding inactive ingredients and allergens in the medicine, 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.

This medicine has been prescribed for you. 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?

The medicine is used for the secondary prevention of atherothrombotic vascular events (heart attacks, cerebral stroke or vascular death) in patients with atherosclerosis who have had a myocardial infarction or ischemic cerebrovascular event or who have a peripheral arterial disease, and in patients with unstable angina pectoris, including patients undergoing catheterization with stent implantation who are being treated with aspirin.

The medicine is used to prevent atherothrombotic and thromboembolic events (heart attacks, cerebral strokes, embolisms or vascular death) in combination with aspirin, in patients suffering from atrial fibrillation-type arrhythmia, who are not suitable for treatment with anticoagulants of the vitamin K antagonist type such as warfarin (Coumadin), antithrombin or anti-factor Xa.

Therapeutic class: Platelet aggregation inhibitors, of the thienopyridine group.

2. BEFORE USING THE MEDICINE Do not use this medicine if:

- You are sensitive (allergic) to clopidogrel or to any of the other components the medicine contains (see section 6).
- You are suffering from a medical condition which is currently causing bleeding, such as: stomach or duodenal ulcer, bleeding within the brain.
- You have a severe hepatic disease. If any of these conditions applies to you, or if you have any doubt, consult with the doctor before taking Clopidogrel Teva.

Special warnings regarding the use of the medicine:

Before treatment with the medicine, tell the doctor if:

- You are at risk for bleeding, such as:
 - A medical condition that puts you at risk for internal bleeding (such as a stomach ulcer).
 - A circulatory system problem that puts you at risk for internal bleeding (internal bleeding in the tissues, organs or joints in your body).
 - You have recently been seriously injured.
 - You have recently undergone surgery (including dental surgery).
 - You are due to undergo surgery (including dental surgery) within the upcoming seven days.
- You have had a blood clot in an artery in your brain (ischemic stroke) in the past seven days.
- You have a renal or hepatic disease.
- You have suffered in the past from an allergic reaction or any reaction to any medicine given to you for treatment of your medical condition.

During treatment with the medicine:

- You should inform your doctor if surgery has been planned for you (including dental surgery).
- You should also inform the doctor immediately if you develop a medical condition (also known as thrombotic thrombocytopenic purpura or TTP), which includes fever and subcutaneous bruises, which may appear as pinpoint red dots, with or without unexplained extreme fatigue, confusion, yellowing of the skin or eyes (jaundice) (see section 4 "Side effects").
- If you injure or cut yourself, it may take longer than usual for the bleeding to stop. This effect is related to the mechanism of action of your medicine, because it prevents the formation of blood clots. In cases of mild cuts or injuries, such as cutting yourself while shaving, there is usually no problem. However, if you are concerned about the bleeding, refer to your doctor immediately (see section 4 "Side effects").
- The doctor may ask you to perform blood tests.

Children and adolescents:

This medicine is not intended for children and adolescents under 18 years of age.

Drug-drug interactions:

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

Certain other medicines may affect the use of Clopidogrel Teva, or the other way around. Especially inform the doctor if you are taking:

- Medicines that may increase your risk of bleeding, such as:
 - Oral anticoagulants, medicines used to reduce blood clotting.
 - Non-steroidal anti-inflammatory drugs (NSAIDs), that are generally used for treatment of pain and/or inflammation of muscles or joints.
 - Heparin or any other injectable medicines used to reduce blood coagulation.
 - Ticlopidine or other antiplatelet medicines.

- Selective serotonin reuptake inhibitors (SSRIs) (including, but not limited to, fluoxetine or fluvoxamine), medicines usually used for treatment of depression.
- Rifampicin (used for treatment of severe infections).
- Omeprazole or esomeprazole, medicines for treatment of abdominal pain.
- Fluconazole or voriconazole, medicines for treatment of fungal infections.
- Efavirenz or other antiretroviral medicines (used for treatment of HIV infection).
- Carbamazepine, a medicine for treatment of certain types of epilepsy.
- Moclobemide, a medicine for treatment of depression.
- Repaglinide, a medicine for treatment of diabetes.
- Paclitaxel, a medicine for treatment of cancer.
- Opioids: while you are treated with clopidogrel, you must inform your doctor before being prescribed any opioid medicine (used for treatment of severe pain).
- Rosuvastatin (used to reduce your cholesterol level).

If you have experienced severe chest pain (unstable angina or a heart attack), you may be prescribed Clopidogrel Teva in combination with acetylsalicylic acid, a substance found in many medicines used to relieve pain and reduce fever. Casual use of acetylsalicylic acid (no more than 1,000 mg in any 24-hour period) should generally not cause problems; however, prolonged use in other situations must be discussed with your doctor.

Use of the medicine and food:

The medicine may be taken with or without food.

Pregnancy, breastfeeding and fertility:

It is preferable not to take the medicine during pregnancy. If you are pregnant or suspect that you are pregnant, tell your doctor or pharmacist before taking Clopidogrel Teva. If you become pregnant while taking this medicine, consult with the doctor immediately since it is not recommended to take clopidogrel during pregnancy.

Do not breastfeed while taking this medicine.

If you are breastfeeding or planning to breastfeed, consult with the doctor before taking the medicine.

Consult with your doctor or pharmacist before taking any medicine.

Driving and operating machinery:

Clopidogrel Teva is not expected to have any effect on your ability to drive or operate machinery.

Important information about some ingredients of the medicine:

- The medicine contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars (such as lactose), contact your doctor before taking this medicine.
- This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor. The usual dosage, including for patients with a condition called "atrial fibrillation" (an irregular heartbeat), is: one tablet of Clopidogrel Teva 75 mg per day, to be taken orally with or without food, and at the same time each day.

If you have experienced severe chest pain (unstable angina or a heart attack), the doctor may instruct you to take a one-time dosage of 300 mg (4 tablets of 75 mg) at the beginning of treatment. Afterwards, the recommended dosage is one Clopidogrel Teva 75 mg tablet once daily, taken as described above.

Do not exceed the recommended dose. You must take Clopidogrel Teva for as long as the doctor prescribes it for you.

Crushing/halving/chewing:

No information is available regarding crushing or pulverizing the tablet. Do not chew! The medicine should be taken with water. The medicine may be taken with or without food.

If you accidentally took a higher dosage:

Refer immediately to a doctor or proceed to the nearest hospital emergency room, because of the increased risk of bleeding.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you. If you forgot to take the medicine:

If you forgot to take a dose of Clopidogrel Teva but remembered within 12 hours of the usual dosing time, take a tablet immediately, and take the next tablet at the usual time.

If you forgot and more than 12 hours have elapsed, just take the next single dose at the usual time. Do not take a double dose in order to compensate for the forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking Clopidogrel Teva: Do not stop taking the medicine unless your doctor has instructed you to do so. Refer to your doctor or pharmacist before discontinuing the treatment. Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any further questions about using the medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Clopidogrel 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.

Consult with the doctor immediately if the following signs appear:

- Fever, signs of infection or extreme fatigue. These may indicate a rare decrease in certain types of blood cells.

- Signs of a liver problem, such as yellowing of the skin and/or eyes (jaundice), whether or not associated with subcutaneous bleeding appearing as pinpoint red dots, and/or confusion (see section 2 "Before using the medicine" under subsection "Special warnings regarding the use of the medicine").
- Swelling of the mouth or skin problems such as rash, itching and skin blisters. These may be the signs of an allergic reaction.

The most common side effect reported with this medicine is bleeding. The bleeding may occur as bleeding in the stomach or intestines, as a bruise, as a hematoma (unusual bleeding or bruising under the skin), as a nose bleed, or as blood in the urine. In a small number of cases bleeding has also been reported in the eye, inside the head, in the lungs or in the joints.

If you suffer from prolonged bleeding during treatment with Clopidogrel Teva: If you injure or cut yourself, it may take longer than usual for the bleeding to stop.

This effect is related to the mechanism of action of your medicine, because it prevents the formation of blood clots. In cases of mild cuts or injuries, such as cutting yourself while shaving, there is usually no problem. However, if you are concerned about the bleeding, refer to your doctor immediately (see section 2 "Before using the medicine" under subsection "Special warnings regarding the use of the medicine").

Other side effects include:

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

Diarrhea, abdominal pain, dyspepsia or heartburn.

Uncommon side effects (can affect up to 1 in 100 users):

Headache, stomach ulcer, vomiting, nausea, constipation, excessive gas in the stomach or intestines, rash, itching, dizziness, sensation of tingling or numbness.

Rare side effects (can affect up to 1 in 1,000 users):

Vertigo, breast enlargement in men.

Very rare side effects (can affect up to 1 in 10,000 users):

Jaundice, severe abdominal pain with or without backache, fever, breathing difficulties sometimes associated with coughing; general allergic reactions (such as overall sensation of heat with sudden general discomfort, which may even lead to fainting), swelling of the mouth, skin blisters, skin allergy, inflammation of the oral mucosa, drop in blood pressure, confusion, hallucinations, arthralgia (joint pain), myalgia (muscle pain), altered sense of taste or loss of the taste of food.

Side effects of unknown frequency (their frequency cannot be estimated from the existing data):

Hypersensitivity reactions accompanied by chest or abdominal pain, symptoms of continuously low blood sugar level.

In addition, the doctor may notice changes in your blood or urine tests.

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 under 25°C.

Do not use the medicine if you observe visible changes in the tablet.

Bottle package: after first opening of the bottle, the medicine can be used up to the expiry date.

Do not flush medicines down the drain or throw them in your domestic trash. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, Clopidogrel Teva also contains:

Microcrystalline Cellulose, Lactose Monohydrate, Hydrogenated Vegetable Oil Type I, Sodium Lauryl Sulfate, Crospovidone, Hydroxypropyl Cellulose, Hypromellose 15 cP/HPMC 2910, Titanium Dioxide, PEG 4000/ Macrogol, Iron Oxide Red, Indigo Carmine

Aluminium Lake/FD&C Blue No. 2, Iron Oxide Yellow.

What does the medicine look like and what are the contents of the package:

- Each package contains light-pink to pink, film-coated, capsule-shaped tablets. One side of the tablet is debossed with the number "93" and the other side of the tablet is debossed with the number "7314".

- Each package contains 30 tablets in a bottle or blister pack.
- Not all package sizes may be marketed.

This leaflet does not contain all of the information regarding the medicine. If you have any question or if you are unsure about something, please refer to the doctor.

Name and address of the manufacturer and marketing authorization holder:

Teva Israel Ltd.

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

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Registration number of the medicine in the national drug registry of the Ministry of Health: 139-40-31295

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