

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

The medicine is dispensed with a doctor's prescription only

Clood Tablets

Active ingredient:

Each **Clood** tablet contains:

Clopidogrel (as hydrogen sulfate) 75 mg

For information on inactive and allergenic ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and 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 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 prevention of atherothrombotic vascular events (heart attacks, cerebral stroke or vascular-related death) in patients with atherosclerosis who have had a myocardial infarction, ischemic stroke or are suffering from peripheral arterial disease, and in patients suffering from unstable angina pectoris, including patients undergoing a stent implant by catheterization and who are being treated with aspirin.

The medicine is used for the prevention of atherothrombotic and thromboembolic events (heart attacks, cerebral stroke, emboli or vascular-related death) in combination with aspirin, in patients suffering from heart rhythm disorder of the atrial fibrillation type, who are not suitable for treatment with anti-coagulants of the vitamin K antagonist type, such as warfarin (Coumadin), anti-thrombin or anti-factor Xa.

Therapeutic group: Platelet aggregation inhibitors from the thienopyridine group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to clopidogrel or to any of the additional ingredients contained in the medicine (see section 6).
- you suffer from a medical condition that presently causes bleeding, such as: peptic or duodenal ulcer, intracranial hemorrhage.
- you suffer from a severe liver disease.

If any of these apply to you, or if you are in any doubt at all, consult your doctor before taking **Clood**.

Special warnings regarding 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 (e.g., peptic ulcer).
 - a problem with the blood system that puts you at risk for internal bleeding (internal bleeding in the tissues, limbs or joints in your body).
 - you have recently had a serious injury.
 - you recently underwent surgery (including dental surgery).
 - you are due to undergo surgery (including dental surgery) within the next seven days.
- If you have had a clot in an artery of your brain (ischemic stroke) which occurred within the last seven days.
- You suffer from kidney or liver disease.
- You have suffered in the past from an allergy or reaction to any medicine used to treat your disease.

During treatment with the medicine

- You must inform the doctor if you are planning to undergo surgery (including dental surgery).
- You must 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 can appear as red pinpoint dots, with or without unexplained extreme fatigue, confusion, yellowing of the skin or eyes (jaundice) (see section 4 – "Side effects").

- If you are injured or wounded, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. There is usually no problem with regard to cuts or mild injuries, such as those caused by shaving. However, if you are bothered by the bleeding, refer to the doctor immediately (see section 4 – "Side effects").

- The doctor may ask you to have blood tests performed.

Children and adolescents

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

Drug interactions

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

Some other medicines may influence the use of **Clood** or vice versa.

In particular, inform the doctor if you are taking:

- Medicines that may increase your risk of bleeding such as:
 - Oral anticoagulants, medicines used to reduce blood coagulation.
 - Non-steroidal anti-inflammatory drugs (NSAIDs), usually used to treat pain and/or inflammation of the muscles or joints.
 - Heparin or any other injectable medicines used to reduce blood coagulation.
 - Ticlopidine, another anti-platelet preparation.
 - Selective serotonin reuptake inhibitors (SSRIs) (including but not restricted to fluoxetine or fluvoxamine), medicines usually used to treat depression.
- Rifampicin, used to treat severe infections.
- Omeprazole, esomeprazole – medicines to treat abdominal pain.
- Fluconazole, voriconazole – medicines to treat fungal infections.
- Efavirenz, or any other anti-retroviral medicines used to treat HIV infection.
- Carbamazepine, a medicine to treat some forms of epilepsy.
- Moclobemide, a medicine given for the treatment of depression.
- Repaglinide, a medicine to treat diabetes.
- Paclitaxel, a medicine to treat cancer.
- Opioids: while you are being treated with clopidogrel, you should inform your doctor before being prescribed any opioid (used to treat severe pain).

If you have experienced severe chest pain (unstable angina or heart attack), the doctor may prescribe for you **Clood** together with acetylsalicylic acid, a substance found in many medicines used in pain relief and fever reduction. Occasional use of acetylsalicylic acid (no more than 1,000 mg in any 24-hour period) should generally not cause a problem, but prolonged use in other circumstances should 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, you should tell your doctor or your pharmacist before taking **Clood**. If you become pregnant while taking the medicine, consult with the doctor immediately as it is recommended not to take clopidogrel while you are pregnant.

Do not breastfeed while taking the medicine.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and operating machinery

It is not expected that **Clood** will affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Clood contains lactose.

If you have been told by your doctor that you have an intolerance to some

sugars (such as lactose), contact your doctor before taking the medicine. **Clood** contains hydrogenated castor oil, which may cause stomach upset or diarrhea.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage [including in the case of atrial fibrillation (irregular heartbeat)] is: one 75 mg tablet per day, to be taken orally with or without food, and at the same time each day.

If you have experienced severe chest pain (a heart attack or unstable angina pectoris), the doctor may instruct you to take a 300 mg dosage (four 75 mg tablets) once only, at the beginning of treatment. Afterwards, the recommended dosage is one **Clood** 75 mg tablet per day, taken as described above.

Do not exceed the recommended dose.

You must take **Clood** for as long as the doctor prescribes it for you.

Swallow the medicine with water.

The medicine may be taken with or without food.

Do not halve the tablet! There is no information regarding crushing or chewing the tablet.

If you accidentally took too high a dose: Refer to the doctor or to a hospital emergency room immediately, due to the increased risk of bleeding. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor 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 a dose of **Clood**, but remember within 12 hours from the regular dosing time, take a tablet immediately and take the next tablet at the regular time.

If you forgot to take the tablet and more than 12 hours have passed, simply take the next single dose at the scheduled time. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking Clood: Do not stop taking the medicine unless the doctor instructed you to do so. Refer to the doctor or pharmacist before stopping treatment.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Clood** 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.

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 blood cells.
- Signs of a liver problem, such as yellowing of the skin and/or eyes (jaundice), with or without association with subcutaneous bleeding, appearing as red pinpoint spots, and/or confusion (see section 2 – "Special warnings regarding use of the medicine").
- Swelling of the mouth, or skin problems such as rash, itching and blisters. These may be signs of an allergic reaction.

The most common side effect reported with Clood is bleeding. The bleeding may occur as bleeding in the stomach or bowels, bruising, or hematoma (unusual bleeding or subcutaneous bruise), as a nosebleed or blood in the urine. In a small number of cases, there were reports of bleeding in the eye, inside the head, in the lungs or in the joints.

If you suffer from prolonged bleeding during treatment with Clood: If you are injured or wounded, it may take longer than usual for bleeding to stop. This is linked to the way your medicine works as it prevents the ability of blood clots to form. There is usually no problem with regard to cuts or mild injuries, such as those caused by shaving. However, if you are bothered

by the bleeding, refer to the doctor immediately (see section 2 – "Special warnings regarding use of the medicine").

Additional side effects include:

Common side effects (may affect up to one user in 10): diarrhea, abdominal pain, dyspepsia or heartburn.

Uncommon side effects (may affect up to one user in 100): headache, peptic ulcer, vomiting, nausea, constipation, excessive gas in stomach or intestines, rash, itching, dizziness, tingling sensation or numbness.

Rare side effects (may affect up to one user in 1,000): dizzy sensation (vertigo), enlarged breasts in males.

Very rare side effects (may affect up to one user in 10,000): jaundice, severe abdominal pain with or without back pain, fever and breathing difficulties sometimes accompanied by coughing, general allergic reactions (for example, sensation of heat with sudden generalized discomfort until fainting), swelling of the mouth, skin blisters, skin allergy, inflammation of the oral mucosa, drop in blood pressure, confusion, hallucinations, joint pain, muscle pain, changes in taste or loss of taste of food.

Side effects whose frequency is unknown (their frequency cannot be estimated from the existing data): hypersensitivity reactions accompanied by chest or abdominal pain, persistent low blood sugar symptoms.

In addition, it is possible that the doctor will notice changes in your blood and urine tests.

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

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 safe place out of the reach and sight of children and/or infants to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by 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.

Storage conditions: Store at a temperature up to 25°C and in a place protected from light.

Do not dispose medicines in the wastewater or household waste bin. Ask your pharmacist how to dispose of medicines that you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Microcrystalline cellulose, Lactose anhydrous, Low-substituted hydroxypropyl cellulose, Glyceryl behenate, Hydrogenated castor oil, Hydroxypropyl methylcellulose, Colloidal silicon dioxide, Opadry orange OY-3569.

What the medicine looks like and the contents of the package:

The medicine is packaged in trays (blisters) inserted into a carton box. **Clood** comes in pack sizes of 10, 20, 30, 60 or 100 tablets.

Not all package sizes may be marketed.

Clood are film-coated, elongated, biconvex, orange tablets.

If you have any question or are uncertain about something, please refer to the doctor.

Registration holder and address: Unipharm Ltd., P.O.Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

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

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