

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr CLOPIDOGREL
Clopidogrel Tablets USP

Read this carefully before you start taking **CLOPIDOGREL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CLOPIDOGREL**.

What is CLOPIDOGREL used for?

- CLOPIDOGREL is used in adults to help prevent blood clots and reduce the risk of having conditions caused by blood clots (such as strokes, unstable angina (chest pain at rest), heart attacks, or peripheral arterial disease (leg pain on walking or at rest)).
- CLOPIDOGREL is also used in adults who have atrial fibrillation (irregular heartbeat) and cannot take medicines known as oral anticoagulants.

How does CLOPIDOGREL work?

CLOPIDOGREL belongs to a group of medicines known as antiplatelet drugs. Platelets are very small structures in the blood that clump together during blood clotting. Antiplatelet drugs such as CLOPIDOGREL help prevent this clumping and reduce the chance of blood clots forming.

What are the ingredients in CLOPIDOGREL?

Medicinal ingredient: Clopidogrel bisulfate

Non-medicinal ingredients: Anhydrous lactose, colloidal silicon dioxide, crospovidone, ferric oxide red, hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, polyethylene glycol, titanium dioxide and zinc stearate.

CLOPIDOGREL comes in the following dosage forms:

Tablets, 75 mg

Do not use CLOPIDOGREL if you:

- are allergic to clopidogrel bisulfate or any of the ingredients contained in the tablets.
- are taking replaglinide, a drug used to lower blood glucose.
- have a medical condition that may cause bleeding, such as a stomach ulcer.
- have liver problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CLOPIDOGREL. Talk about any health conditions or problems you may have, including if you:

- have a medical condition that causes bleeding, such as a stomach ulcer, or a blood disorder that causes you to bleed more easily or tend to bleed longer than 10 minutes without taking any drugs.
- are taking any other medications such as:

- acetylsalicylic acid (ASA);
 - other drugs used to reduce blood clotting, such as warfarin, heparin, abciximab, eptifibatide and tirofiban;
 - oral antidepressants drugs (SSRIs – Selective Serotonin Reuptake Inhibitors), such as fluvoxamine and fluoxetine;
 - Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) used to treat painful and/or inflammatory conditions of muscles or joints;
 - drugs used to treat stomach ulcers and stomach acidity, such as omeprazole;
 - rifampin, an antibiotic used to treat strong infections.
- have kidney problems.
 - are pregnant or become pregnant while taking CLOPIDOGREL.
 - are breast-feeding.
 - have recently had surgery (including dental surgery), or plan on having surgery soon. Your healthcare professional may ask you to stop taking CLOPIDOGREL for 5-7 days before your surgery.
 - have allergies to medications, including prasugrel or ticlopidine.
 - are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption
 because lactose is a non-medicinal ingredient in CLOPIDOGREL.

Other warnings you should know about:

CLOPIDOGREL is not recommended for children or adolescents below 18 years of age.

If you experience any excessive bleeding while taking CLOPIDOGREL, do not stop taking CLOPIDOGREL but see or call your healthcare professional right away.

If you should see another doctor or a dentist while you are using CLOPIDOGREL, you should tell them that you are using CLOPIDOGREL.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CLOPIDOGREL:

- Aspirin (ASA), used to treat pain, fever and inflammation.
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), used to treat painful and/or inflammatory conditions of the muscles or joints.
- Opioids, used to treat severe pain. While you are treated with CLOPIDOGREL, you should tell your healthcare professional before being prescribed any opioid.
- Selective Serotonin Reuptake Inhibitors (SSRIs), such as fluvoxamine and fluoxetine, used to treat depression.
- Drugs use to reduce clotting, such as heparin, warfarin, abciximab, eptifibatide, and tirofiban.
- Antacids, such as omeprazole, used for indigestion or heartburn.
- Repaglinide, used to lower blood glucose.
- Paclitaxel, used to treat many types of cancer.

- Rifampin, an antibiotic used to treat severe infections.

How to take CLOPIDOGREL:

CLOPIDOGREL can be taken with or without food. You should take your medicine regularly and at the same time each day.

This product has been prescribed for you. You should not give it to others. CLOPIDOGREL should be taken long term, under the supervision of your healthcare professional.

Usual adult dose:

You should take one 75 mg tablet of CLOPIDOGREL per day, by mouth.

If you have had unstable angina (chest pain at rest) or a heart attack, a one-time 300 mg dose may be given to you, followed by one 75 mg tablet daily.

If you have atrial fibrillation (irregular heartbeat), the usual dose is CLOPIDOGREL 75 mg once daily in combination with ASA 75-100 mg once daily.

Overdose:

If you think you, or a person you are caring for have taken too much CLOPIDOGREL, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of CLOPIDOGREL, but remember within 12 hours of your usual time, take your tablet immediately, and then take your next tablet at the normal time. If you forget for more than 12 hours, simply take the next single dose at the usual time. Do not take a double dose to make up for the one you missed.

When using the blister format, you can check the day on which you last took a tablet of CLOPIDOGREL by referring to the calendar printed on the blister strip.

What are possible side effects from using CLOPIDOGREL?

These are not all the possible side effects you may feel when taking CLOPIDOGREL . If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- joint pain and/or muscle pain
- abdominal pain, diarrhea, indigestion (heartburn)
- nausea, vomiting, constipation, loss of taste, taste disturbance
- dizziness, headache
- tingling sensation in the arms and/or legs
- rash, itching

- bruising
- enlargement of breast tissue in men

If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. For minor cuts and injuries, like cutting yourself while shaving, this is of no concern. However, if you are in any doubt at all, you should contact your healthcare professional immediately.

CLOPIDOGREL can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Nose bleeds	✓		
Bleeding disorders: blood in the stool, urine or eye, vomiting blood, coughing up blood, purple spotted rash			✓
Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
UNCOMMON			
Fever, signs of infection, extreme tiredness			✓
Liver disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite			✓
Bleeding in the brain: sudden, severe headache, weakness, loss of speech or vision, confusion, nausea, vomiting, seizures, loss of consciousness			✓
VERY RARE			
Eosinophilic pneumonia: cough, fever, difficulty breathing, and sweating at night		✓	
Kounis syndrome: a mixture of symptoms and signs of an allergic reaction and heart attack or unstable angina, with chest pain, shortness of breath, faintness, nausea, vomiting, fainting, itching, hives, sudden,			✓

heavy sweating, unusual paleness, palpitations, low blood pressure, slow heartbeat			
UNKNOWN			
Low blood sugar: sweating, shakiness, dizziness, headache, and blurred vision		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature between 15°C and 30°C.

CLOPIDOGREL tablets should be stored in a safe place and be kept out of the reach and sight of children. Do not leave them near a radiator, on a window sill or in a humid place. Do not remove tablets from the packaging until you are ready to take them.

If you want more information about CLOPIDOGREL:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>). Find the Patient Medication Information on the manufacturer's website (www.sivem.ca), or by calling 1-855-788-3153.

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