

PART III: CONSUMER INFORMATION**PrCLOPIDOGREL
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.

ABOUT THIS MEDICATION**What the medication is used for:**

You have been prescribed CLOPIDOGREL because you are at risk for experiencing unwanted blood clots (thrombi). These blood clots can lead to symptoms which present in different manners, such as strokes, unstable angina, heart attacks, or peripheral arterial disease (leg pain on walking or at rest). CLOPIDOGREL is taken to prevent further blood clots from forming thereby reducing the risk of having unstable angina, a heart attack or another stroke.

Your doctor can also prescribe CLOPIDOGREL for you if you have an irregular heartbeat, a condition called 'atrial fibrillation', and you cannot take medicines known as 'oral anticoagulants' (for example, warfarin) which prevent new clots from forming and prevent existing clots from growing. You should have been told that 'oral anticoagulants' are more effective than acetylsalicylic acid (ASA) or the combined use of CLOPIDOGREL and ASA for this condition. Your doctor should have prescribed CLOPIDOGREL plus ASA if you cannot take 'oral anticoagulants' as the combined use of CLOPIDOGREL plus ASA is more effective than ASA alone.

Be sure to talk to your doctor before taking CLOPIDOGREL if you have an elevated risk of bleeding.

This product has been prescribed for you personally and you should not pass it on to others.

What it does:

CLOPIDOGREL tablets belong to a group of medicines called antiplatelet drugs. Platelets are very small structures in blood, smaller than red or white blood cells, which clump together during blood clotting. By preventing this clumping, antiplatelet drugs reduce the chances of blood clots forming (a process called thrombosis).

When it should not be used:**Do not take CLOPIDOGREL if you:**

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

What the medicinal ingredient is:

Clopidogrel bisulfate

What the nonmedicinal ingredients are:

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

What dosage forms it comes in:

Tablets: 75 mg

WARNINGS AND PRECAUTIONS**BEFORE you use CLOPIDOGREL talk to your doctor or pharmacist if you:**

- have a medical condition that is causing 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, fluoxetine,
 - Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) used to treat painful and/or inflammatory conditions of muscles or joints
- are taking drugs used to treat stomach ulcers and stomach acidity (e.g. omeprazole).
- are pregnant or become pregnant on CLOPIDOGREL, or you are breast-feeding.
- have recently undergone surgery (including dental surgery).
- will be having surgery. Your doctor may ask you to stop taking CLOPIDOGREL for 5 to 7 days before your surgery.
- have allergies to medications including prasugrel or ticlopidine.

CLOPIDOGREL is not recommended for children or

adolescents below 18 years of age.

While you are on CLOPIDOGREL if you experience any excessive bleeding, do not stop taking CLOPIDOGREL but see or call your doctor right away.

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

INTERACTIONS WITH THIS MEDICATION

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

Drugs that may interact with CLOPIDOGREL include:

- 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: while you are treated with CLOPIDOGREL, you should inform your doctor before being prescribed any opioid (used to treat severe pain),
- Selective Serotonin Reuptake Inhibitors (SSRIs), such as fluvoxamine, fluoxetine, used to treat depression,
- Drugs use to reduce clotting, such as heparin, warfarin, abciximab, eptifibatide, and tirofiban,
- Antacids (e.g. omeprazole) used for indigestion or heartburn,
- Repaglinide, a drug used to lower blood glucose in diabetics,
- Paclitaxel, used to treat many types of cancer.

PROPER USE OF THIS MEDICATION

Usual adult dose:

Adults (including the elderly):

You should take one 75 mg tablet of CLOPIDOGREL per day, by mouth. CLOPIDOGREL can be taken with or without food. You should take your medicine regularly and at the same time each day. If you have had unstable angina or a heart attack, a one-time 300 mg dose may be administered followed by one 75 mg tablet daily.

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

CLOPIDOGREL should be taken long term under supervision of your doctor.

Overdose:

If you think you 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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, e.g. cutting yourself shaving, this is of no concern. However, if you are in any doubt at all, you should contact your doctor immediately.

If any of these affects you severely, tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your healthcare professional		Stop taking drug and seek 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		✓	

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	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, syncope, pruritus, urticaria, sudden, heavy sweating, unusual paleness, palpitations, hypotension, slow heartbeat.			✓
Unknown	Persistent low blood sugar symptoms such as: sweating, shakiness, dizziness, headache, and blurred vision.		✓	

This is not a complete list of side effects. For any unexpected effects while taking CLOPIDOGREL, contact your doctor or pharmacist.

HOW TO STORE IT

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.

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.

MORE INFORMATION

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 Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Consumer Information on the manufacturer's website (<http://www.prodoc.qc.ca>) or by contacting Pro Doc Ltée at 1-800-361-8559 or info@prodoc.qc.ca.

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