

PART III: CONSUMER 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.

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.

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 repaglinide, 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, red ferric oxide 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, eptifibatid 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 5-7 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

IMPORTANT: PLEASE READ

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,
- 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.

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			✓
Uncommon	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Fever, signs of infection, extreme tiredness			✓

IMPORTANT: PLEASE READ

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	
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, syncope, pruritus, urticaria, sudden, heavy sweating, unusual			✓

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	
paleness, palpitations, hypotension, slow heartbeat.			

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.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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by
Pro Doc Ltée
Laval, Quebec
H7L 3W9.

Last revised: October 1, 2018