

PART III: CONSUMER INFORMATION**Pr APO-CLOPIDOGREL
Clopidogrel Tablets USP**

This leaflet is part III of a three-part “Product Monograph” published when APO-CLOPIDOGREL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-CLOPIDOGREL. Contact your doctor or pharmacist if you have any questions about the drug.

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

You have been prescribed APO-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). APO-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 APO-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:

APO-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:

- If you are allergic to any of the substances contained in the tablets (see below).
- If you have a medical condition that may cause bleeding, such as a stomach ulcer.
- If you have liver disease or damage.

What the medicinal ingredient is:

Clopidogrel bisulfate

What the nonmedicinal ingredients are:

anhydrous lactose, methylcellulose, crospovidone, colloidal silicon dioxide, zinc stearate, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, polyethylene glycol, titanium dioxide and red ferric oxide (orange shade).

What dosage forms it comes in:

APO-CLOPIDOGREL comes as 75 mg tablets. APO-CLOPIDOGREL tablets are pink, round, film-coated and engraved with “CL” over “75” on one side and “APO” on the other side.

WARNINGS AND PRECAUTIONS

Before you use APO-CLOPIDOGREL talk to your doctor or pharmacist if:

- You have had an allergic reaction to any of the substances contained in the tablets.
- You have a medical condition that is causing bleeding, such as a stomach ulcer.
- You are taking any other medications (such as acetylsalicylic acid (ASA), other drugs used to reduce blood clotting such as warfarin and heparin or Non-Steroidal Anti-Inflammatory Drugs [NSAIDs; drugs used to treat painful and/or inflammatory conditions of muscles or joints]), including those that you buy without a prescription.
- You are taking drugs used to treat stomach ulcers and stomach acidity (e.g. omeprazole).
- You are pregnant or become pregnant on APO-CLOPIDOGREL, or you are breast-feeding
- You have a recent serious injury.
- You have liver disease or damage.
- You have recently undergone surgery (including dental surgery).
- You will be having surgery. Your doctor may ask you to stop taking APO-CLOPIDOGREL for 5-7 days before your surgery.
- You have a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body) or tend to bleed longer than 10 minutes without taking any drugs.

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

While you are on APO-CLOPIDOGREL it is important that you do not take any medicine other than that prescribed by your doctor. If you should see another doctor or a dentist while you are using APO-CLOPIDOGREL, you should inform them that you are using APO-CLOPIDOGREL.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with APO-CLOPIDOGREL include: ASA, NSAIDs, heparin, warfarin, digoxin, theophylline, antacids (e.g. omeprazole).

PROPER USE OF THIS MEDICATION**Usual dose:**

Adults (Including the elderly):

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

Children and adolescents:

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

IMPORTANT: PLEASE READ

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

Overdose:

A large dose of tablets could put you at risk of serious bleeding, requiring emergency treatment.

In case of drug overdose, contact a health care practitioner, 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 APO-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

Occasional side effects reported with APO-CLOPIDOGREL are:

- Rashes and/or itching
- Diarrhea
- Abdominal pain
- Indigestion or heartburn
- Constipation
- Bleeding in the stomach, bowels or into the eye
- Hepatic (liver) and biliary (bile) disorders
- Blood in the urine (haematuria)
- Generalized allergic reactions such as swelling of the face, lips and/or tongue, shortness of breath
- Bleeding from blood vessels inside the head has been reported in a very small number of cases.

In very rare cases, joint pain and /or muscle pain are reported.

Contact immediately your doctor if you experience;

- Fever, signs of infection or extreme tiredness. This may be due to rare decrease of some blood cells.
- Signs of liver problems such as yellowing of the skin and/or eyes (jaundice), whether or not associated with bleeding and/or confusion.

If you notice any undesirable effects, especially during the first few weeks of treatment, including any not mentioned above, promptly notify your doctor for assessment and follow-up.

If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop. This is linked to the way your medicine works. 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.

Your ability to drive or operate complicated machinery should not be affected

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Abdominal pain		✓	
	Diarrhea		✓	
	Indigestion		✓	
	Bruising		✓	
	Nose bleeds		✓	
	Bleeding in stomach, bowels		✓	
Uncommon	Fever, signs of infection, extreme tiredness, signs of liver problems		✓ Immediately	
	Nausea		✓	
	Constipation		✓	
	Vomiting		✓	
	Bleeding in the eye		✓	
	Dizziness		✓	
	Headache		✓	
	Tingling sensation		✓	
	Rash		✓	
	Itching		✓	

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

HOW TO STORE IT

APO-CLOPIDOGREL tablets should be stored in a safe place and be kept out of the reach 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.

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701 E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:
<http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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