Apo-Clopidogrel 75mg film-coated tab

Clopidogrel Bisulfate

What is in this leaflet

This leaflet answers some of the common questions people ask about APO-CLOPIDOGREL. It does not contain all the information that is known about APO-CLOPIDOGREL.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking APO-CLOPIDOGREL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is the medication 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.

How it works

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).

Before you use

When you must not take it

- If you are allergic to any of the substances contained in the tablets.
- If you have a medical condition that is causing bleeding, such as a stomach ulcer.
- If you have liver disease or damage.

Before you start to take it

Tell your doctor or pharmacist if:

- You are pregnant or become pregnant on APO-CLOPIDOGREL, or you are breast-feeding
- You have a recent serious injury.
- 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.

Taking other medicines

Drugs that may interact with APO-CLOPIDOGREL include: ASA, NSAIDS, heparin, warfarin, digoxin, theophylline, antacids.

How to take

How much to take

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. 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.

When to take it

You should take your medicine regularly and at the same time each day.

How long to take it

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

If you forget to take it

Do not worry. Take your recommended dose as soon as you remember, unless it is nearly time for the next dose. Then take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you take too much (overdose)

If you have accidentally taken more than your prescribed dose, contact your nearest casualty department or tell your doctor or pharmacist immediately. Remember to take the pack and any remaining tablets with you.

While you are using it

Things you must do

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.

Things you must not do

While you are on APO-CLOPIDOGREL it is important that you do not take any medicine other than that prescribed by your doctor.

Things to be careful of

None

Side effects

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
- Liver and bile disorders
- Blood in the urine
- Generalized allergic reactions such as swelling of the face, lips and/or tongue, shortness of breath
- Bleeding from blood vessels inside the head

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 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.

After using this medication

Storage

Remember to keep APO-CLOPIDOGREL and all medications safely away from children.

Do not use this medicine after the month and year written after EXP on the container.

Store APO-CLOPIDOGREL at room temperature (below 25°C).

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product Description

What it looks like?

APO-CLOPIDOGREL tablets are reddish-brown, round, film-coated and engraved with "CL" over "75" on one side and "APO" on the other side.

Available in blister packs of 30's.

Ingredients

Each APO-CLOPIDOGREL tablet contains clopidogrel bisulfate as the active ingredient.

Other important non-medicinal 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).

Malaysian Registration Number

MAL 07090937A

Manufacturer

Apotex Inc. 150 Signet Drive Weston Toronto Ontario M9L 1T9 Canada

Marketing Authorization Holder

Pharmaforte (M) Sdn Bhd 2, Jalan PJU 3/49 Sunway Damansara 47810 Petaling Jaya

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