APO-TICLOPIDINE

Ticlopidine Hydrochloride (250mg)

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What Apo-Ticlopidine is used for

Apo-Ticlopidine is used to reduce the risk of stroke for people who have had a stroke or have particular risk factors for stroke.

How Apo-Ticlopidine works

Apo-Ticlopidine belongs to the class of medications called platelet aggregation inhibitors or antiplatelets.

Apo-Ticlopidine reduces the ability of blood platelets to stick to each other and to the walls of blood vessels. This action reduces the tendency of blood to clot in unwanted places such as in narrowed blood vessels.

Before you use Apo-Ticlopidine

When you must not use it

Do not use Apo-Ticlopidine if you:

- are allergic to Ticlopidine Hydrochloride or any ingredients in this medication.
- have certain medication condition such as :
- *hematopoietic disorders (a type of blood cell disorder)
- *presence of hemostatic disorder (Bleeding retardation mechanism disorder)
- *conditions associated with active bleeding (such as bleeding ulcer in the stomach or brain)
- *severe liver problem.

Always consult a doctor before you consider taking this medication.

Pregnancy and lactation

Do not take Apo-Ticlopidine if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Apo-Ticlopidine if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Inform the doctor if you have just encounter a trauma as there is a danger of abnormal bleeding if Apoticlopidine is given to you.

Your doctor needs to know if you have any other medical condition or any medical history that involves your heart, kidney, liver, or any known blood disorder.

There are certain medication conditions that will harm you if you take this medication without informing a medical professional. Refer to "When you must not use it" for certain conditions that might cause critical harm to you.

You should also let your doctor know if you are undergoing and/or have just done any operation.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

There are medications that might interfere with Apo-Ticlopidine when taken together, which includes:

- other antiplatelet medicines
- non-steroidal anti-inflammatory medicines (NSAIDs) that commonly used for pain and inflammation
- warfarin (a blood thinning agent)
- theophylline (medicine used for asthma)
- digoxin (for heart problem)
- cimetidine (for gastric problem)

Please refer to your doctor/pharmacist for a more detail and complete list of medicines that might interact with Apo-ticlopidine if taken together.

How to use Apo-Ticlopidine

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose of Apo-Ticlopidine is 250mg twice daily.

- When to use it

Use as directed by your doctor or pharmacist.

Take Apo-Ticlopidine with food. Apo-Ticlopidine should be taken with meals to minimize gastrointestinal intolerance.

- How long to use it

Continue taking Apo-Ticlopidine for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Ticlopidine.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Apo-Ticlopidine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Apo-ticlopidine may cause:

- neutropenia (reduced white blood cells that will lead to fever, chills, sore throat
- thrombocytopenia (reduced blood platelet that will increase the risk of bleeding)
- anemia (reduced red blood cells)
- purpura (red or purple spots visible through your skin)
- bleeding disorders(such as unusual bleeding, bruising, dark stool)

Inform your doctor immediately if you find any of the above happens to you. The doctor will decide whether you should stop taking Apo-ticlopidine.

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Apo-Ticlopidine can cause side effects, although not everybody gets them.

Common side effects might include stomach discomfort, nausea, diarrhea, or skin rashes.

Other side effects include liver abnormalities and jaundice (dark urine and light colored stool)

Visit your doctor or pharmacist immediately if you experience any side effects whether listed above or not after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers → Reporting).

Storage and Disposal of Apo-Ticlopidine

- Storage

Keep out of the reach and sight of children.

Store between 15-25°C, away from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
Oval, white, biconvex, film-coated tablet, engraved "APO" on one side and "250" on the other side.

- Ingredients

- Active ingredient Ticlopidine Hydrochloride
- Inactive ingredients
 Microcrystalline cellulose,
 croscarmellose sodium, stearic acid,
 hydroxypropyl methylcellulose,
 polyethylene glycol, titanium
 dioxide and carnauba wax.

- MAL number:

MAL 20021575A

Manufacturer

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

Product Registration Holder

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

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