

APO-Clopidogrel Tablets

Contains the active ingredient, clopidogrel

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about clopidogrel.

It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What clopidogrel is used for

The name of your medicine is APO-Clopidogrel. It contains the active ingredient, clopidogrel.

It is used to prevent blood clots forming in hardened blood vessels (a process known as atherothrombosis) which can lead to events such as stroke, heart attack or death.

How it works

Clopidogrel belongs to a group of medicine called anti-platelet medicines.

Platelets are very small blood cells which clump together during blood clotting. By preventing this clumping, anti-platelet medicines reduce the chances of blood clots forming (a process called thrombosis).

You may have been prescribed clopidogrel to help prevent blood clots forming and to reduce the risk of stroke, heart attack or death because:

- you have previously suffered a heart attack, stroke or have a condition known as peripheral arterial disease (leg pain on walking or at rest).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed clopidogrel for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

Use in children

There is not enough information to recommend the use of this medicine in children.

Before you take clopidogrel

When you must not take it

Do not take this medicine if you have had an allergic reaction to clopidogrel or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine if you have any of the following:

- a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head
- severe liver disease

Do not take this medicine if you are breast-feeding.

Clopidogrel passes into breast milk and, therefore, there is the possibility that the breast-fed baby may be affected

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- bleeding disorders or blood clotting problems
- any illness or disability that was caused by bleeding, for example impaired sight or vision because of bleeding within eye
- recent serious injury
- recent surgery (including dental surgery)
- any form of liver disease
- a genetic condition which means that a certain enzyme (CYP2C19) in your liver works differently.

3. You plan to become pregnant or breast-feed.

Your doctor will discuss the possible risks and benefits of taking clopidogrel during pregnancy. As discussed above, breast-feeding is not recommended whilst taking this medicine.

4. You are planning to have an operation (including dental surgery) in the next two weeks.

Your doctor will decide whether or not you need to stop clopidogrel prior to surgery.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and clopidogrel may interfere with each other. These include:

- medicines used to treat or prevent blood clots, for example: aspirin, heparins, warfarin and ticlopidine. There may also be others.
- non-steroidal anti-inflammatory drugs (NSAIDs) medicines used to treat arthritis, period pain, inflammation, aches and pain
- phenytoin, a medicine used to treat epilepsy
- tolbutamide, a medicine used to treat diabetes
- tamoxifen, a medicine used to treat breast cancer
- fluvastatin, a medicine used to lower cholesterol
- medicines which may affect the liver enzyme in your body which makes clopidogrel work. Examples include omeprazole and lansoprazole (used to treat stomach problems); letrozole and bicalutamide (used to treat certain cancers), and fluvoxamine (used to treat depression). These may stop clopidogrel working properly. There may also be others.

These medicines may be affected by clopidogrel or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these

medicines. They may also have more information on medicines to be careful with or avoid while taking clopidogrel.

Other interactions not listed above may also occur.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The usual dose of clopidogrel is one 75 mg tablet daily.

Your clopidogrel tablets are provided in a calendar pack which is designed to remind you when to take this medication.

To do this, take your first dose from the position marked "First Day ". On the following day take the first tablet which is labelled with the appropriate day. When you have taken all doses in this pack, take your next prescription in the same way.

How to take it

Swallow the tablet with a glass of water.

Do not crush or chew the tablets.

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much clopidogrel.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much clopidogrel, you may experience excessive bleeding (see Side Effects section).

While you are taking clopidogrel

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking clopidogrel.

It may increase the risk of bleeding during an operation or some dental work. Therefore, treatment may need to be stopped before surgery. Your doctor will decide whether to stop clopidogrel and if so, how long before surgery or dental work.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up and have any blood tests promptly if your doctor orders them.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Tell your doctor if you decide to breast-feed your baby. Your doctor may want to discuss this and change your medicine.

Remind your doctor that you are taking clopidogrel if you are about to start on any new medicine.

Ask your doctor whether there are any activities you should avoid while taking clopidogrel, for example certain sports.

Sometimes after an injury, bleeding may occur inside your body without you knowing about it.

Tell your doctor immediately if you are injured while taking clopidogrel.

It may take longer than usual to stop bleeding while you are taking it.

Tell your doctor immediately if you notice any of the following:

- abnormal bruising or bleeding
- abnormal nose bleeds
- bloody or black bowel motions

- red or purple blotches on your skin
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing (see also "Side Effects" section).

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how clopidogrel affects you.

As with other medicines, clopidogrel may cause faintness or dizziness in some people. Make sure you know how you react to the medicine before you drive a car or operate machinery, or do anything else that could be dangerous if you are faint or dizzy. If this occurs, do not drive. If you drink alcohol, faintness or dizziness may be worse.

Side effects of clopidogrel

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking clopidogrel.

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this

list. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea
- itching
- pain or stiffness in the joints
- things taste different.

The above list includes the more common side effects. Mostly, these are mild.

Tell your doctor immediately if you notice any of the following:

(Note: if you take both clopidogrel and aspirin, the risk of side effects related to bleeding may be increased)

- bloody or black bowel motions
- diarrhoea with blood, mucus, stomach pain and fever
- abdominal or stomach pain
- vomiting of blood or vomit that looks like coffee grounds
- coughing up blood
- blood in the urine
- unusually heavy bleeding or oozing from cuts or wounds
- bleeding (including nose bleeds) or bruising more easily than normal
- unusually heavy or unexpected menstrual bleeding
- nausea or vomiting
- headache (severe and continuing)
- faintness or dizziness
- light-headedness or blurred vision
- confusion or hallucinations
- fever or other signs of infection, such as a sore throat
- chills, sweating or clammy skin
- fever, muscle weakness, loss of appetite and fatigue
- muscle pain
- weight loss
- anaemia (being tired and looking pale)
- red or purple spots visible through your skin

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

Symptoms of an allergic reaction such as:

- shortness of breath, tight chest, wheezing or difficulty breathing
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, or swelling of other parts of the body
- muscle pain or tenderness or joint pain
- rash, itching or hives on the skin, or inflamed, cracking or red skin.

Symptoms of severe liver effects such as:

- yellowing of the skin or the whites of the eyes, pale stools and dark urine with vomiting and stomach pain

Other side effects such as:

- blood in the eyes
- numbness (paralysis) or problem with co-ordination
- slurred speech or other difficulty in speaking

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APO-Clopidogrel looks like

APO-Clopidogrel 75 mg is a reddish brown, round biconvex film-coated tablets, imprinted "APO" on one side and "CL" over "75" on the other side.

Blister packs of 28 tablets.

Bottles of 28 and 500 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 75 mg of clopidogrel.

It also contains the following inactive ingredients:

- anhydrous lactose
- methylcellulose
- crospovidone
- colloidal anhydrous silica
- zinc stearate
- hydroxypropylcellulose
- hypromellose
- macrogol 8000
- titanium dioxide
- iron oxide red.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Clopidogrel 75 mg tablets
(blister pack): AUST R 129641

APO-Clopidogrel 75 mg tablets
(bottle): AUST R 129642

Sponsor

Apotex Pty Ltd
66 Waterloo Road
North Ryde, NSW 2113
Australia

Apotex Pty Ltd is the licensee of the registered trademarks APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was prepared in:
September 2010.