

APO-Clopidogrel/Aspirin 75/75 APO-Clopidogrel/Aspirin 75/100 Tablets

Contains the active ingredients clopidogrel (as clopidogrel hydrogen sulfate) and aspirin

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.

This leaflet answers some common questions about Clopidogrel/Aspirin. 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. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Clopidogrel/Aspirin 75/75 APO-Clopidogrel/Aspirin 75/100. It contains the active ingredients clopidogrel (as clopidogrel hydrogen sulfate) and aspirin.

- 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.

You may have been prescribed Clopidogrel/Aspirin to help prevent blood clots forming and to reduce the risk of heart attack, stroke or death, because you have suffered a severe type of chest pain called unstable angina, or had a heart attack.

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

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

How it works

This medicine belongs to a group of medicines 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).

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children as its safety and effectiveness in children have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant.**
Clopidogrel/Aspirin may affect your developing baby if you take it during pregnancy.
- **You are breast-feeding.**
Clopidogrel/Aspirin may pass into human breast milk.
- **You have or have had any of the following:**
 - a medical condition that causes bleeding such as a haemophilia, stomach ulcer or bleeding within your head or bowel
 - erosive gastritis
 - severe liver or kidney disease
 - asthma with rhinitis and/or nasal polyps
 - mastocytosis
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive to or have had an allergic reaction to clopidogrel, aspirin, other salicylates, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, 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 the eye
 - stroke
 - recent serious injury
 - recent surgery (including dental surgery)
 - liver or kidney disease
 - stomach ulcers or other problems with your digestive system
 - inherited diseases causing galactose intolerance
 - gout
 - asthma or allergies
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst in the third trimester of pregnancy. Your doctor will discuss the possible risks and benefits when this medicine is taken during pregnancy.

4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with Clopidogrel/Aspirin. These include:

- aspirin and other salicylates
- clopidogrel
- other medicines used to prevent blood clots, such as heparins and warfarin
- thrombolytic agents, medicines used to break down blood clots
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), medicines used to treat arthritis, period pain, aches and pains
- steroids, including hydrocortisone
- uricosuric medicines, which may be used to treat gout, such as probenecid
- methotrexate, a medicine used to treat cancer or arthritis
- bupropion, fluoxetine, fluvoxamine and moclobemide, medicines used to treat depression
- omeprazole, esomeprazole, lansoprazole and pantoprazole, medicines known as proton pump inhibitors used to prevent gastric reflux
- cimetidine, a medicine used to treat stomach ulcers
- phenytoin, diazepam, carbamazepine, oxcarbazepine, medicines used to treat epilepsy
- tolbutamide and chlorpropamide, medicines used to treat diabetes
- tamoxifen, a medicine used to treat breast cancer
- fluvastatin, a medicine used to lower cholesterol
- voriconazole and fluconazole, medicines used to treat fungal infections
- ciprofloxacin and chloramphenicol, antibiotic medicines
- spironolactone, a diuretic medicine
- ACE inhibitors or angiotensin receptor antagonists plus a thiazide diuretic. These medicines are used to treat high blood pressure and in some cases may be used together to treat other cardiovascular diseases.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with Clopidogrel/Aspirin.

Your doctor will have more information on medicines to avoid or be careful of while taking Clopidogrel/Aspirin.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Clopidogrel/Aspirin is to be used under medical supervision only.

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose of Clopidogrel/Aspirin is one tablet daily.

You may receive a starting dose of 300 mg clopidogrel plus an aspirin tablet. Long term treatment is continued with one Clopidogrel/Aspirin tablet daily.

Should your doctor require you to take higher doses of aspirin you will be switched to separate tablets and no longer take Clopidogrel/Aspirin.

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

How to take it

You should swallow the tablet with a glass of water.

When to take it

Take Clopidogrel/Aspirin during or immediately after a meal.

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

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 to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Take Clopidogrel/Aspirin exactly as your doctor has prescribed and have any blood tests ordered by your doctor promptly.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital
- if you are injured while taking Clopidogrel/Aspirin.
It may take longer than usual to stop bleeding while you are taking Clopidogrel/Aspirin. Sometimes after an injury, bleeding may occur inside your body without you knowing about it.
Ask your doctor whether there are any activities you should avoid while taking Clopidogrel/Aspirin, for example certain sports.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Clopidogrel/Aspirin may increase the risk of bleeding during surgery or some dental work and treatment may need to be stopped beforehand.

Your doctor will decide whether to stop Clopidogrel/Aspirin and if so, how long before surgery or dental work.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

As with other medicines, Clopidogrel/Aspirin may cause faintness or dizziness in some people. If you drink alcohol, faintness or dizziness may be worse.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Clopidogrel/Aspirin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following.

This list includes the more common side effects. Mostly, these are mild:

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

Tell your doctor as soon as possible if you notice any of the following.

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

- blood or black bowel motions
- diarrhoea with blood, mucus, stomach pain and fever
- abdominal pain or stomach pain
- heartburn
- vomiting of blood or vomit that looks like coffee grounds
- coughing up blood
- blood in the urine
- blood in the eyes
- 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
- numbness (paralysis) or problems with co-ordination
- nausea or vomiting
- faintness or dizziness
- light-headedness or blurred vision
- slurred speech or other difficulty in speaking
- headache (severe and continuing)
- confusion or hallucinations
- fever or other signs of infection, such as sore throat
- rash or hives
- 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
- itching, inflamed, cracking or red skin
- tightness of the chest, wheezing, coughing or difficulty breathing
- yellowing of the skin or the whites of the eyes, pale stools and dark urine with vomiting and stomach pain.

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

Allergic reactions

If you think you are having an allergic reaction to Clopidogrel/Aspirin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms.

Storage and disposal

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 and protected from moisture.

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 this medicine 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, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Clopidogrel/Aspirin 75/75 looks like

75mg/75mg tablets: Yellow, oval, biconvex coated tablet. Engraved "75-75" on one side, "APO" on the other side.

What APO-Clopidogrel/Aspirin 75/100 looks like

75mg/100mg tablets: Light pink, oval biconvex coated tablets, engraved "APO" on one side, "75-100" on the other side

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

Ingredients

- Each APO-Clopidogrel/Aspirin 75/75 tablet contains 75mg of Clopidogrel (as clopidogrel hydrogen sulfate) and 75mg Aspirin as the active ingredients.
- Each APO-Clopidogrel/Aspirin 75/100 tablet contains 75mg of Clopidogrel (as clopidogrel hydrogen sulfate) and 100mg Aspirin as the active ingredients.

It also contains the following inactive ingredients:

- lactose anhydrous
- methylcellulose
- crospovidone
- colloidal anhydrous silica
- zinc stearate
- microcrystalline cellulose
- maize starch
- iron oxide yellow
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide red (Clopidogrel/Aspirin 75/100 only)

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

Australian Registration Numbers

- APO-Clopidogrel/Aspirin 75/75 tablets (blisters of 2, 4, 7, 14, 28, 30, 50, 56, 84): AUST R 201680.
- APO-Clopidogrel/Aspirin 75/75 tablets (bottles of 280): AUST R 201684.
- APO-Clopidogrel/Aspirin 75/100 tablets (blisters of 2, 4, 7, 14, 28, 30, 50, 56, 84): AUST R 190326.

- APO-Clopidogrel/Aspirin 75/100 tablets (bottles of 280): AUST R 190325.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park, 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 last updated in February 2015.