

APO-Clopidogrel/ Aspirin Film Coated Tablets

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.

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.

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

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. It contains the active ingredients clopidogrel (as clopidogrel hydrogen sulfate) and aspirin.

Clopidogrel/Aspirin 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.

Clopidogrel/Aspirin 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).

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 have 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.

There is no evidence that this medicine is addictive.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing clopidogrel or aspirin
- any other similar medicines such as salicylates or anti-inflammatory (NSAIDs)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

Do not take this medicine if you are pregnant.

Do not take clopidogrel/aspirin during the third trimester of pregnancy.

It is not known whether clopidogrel/aspirin may affect your developing baby if you take it during the first two trimesters of pregnancy. Your doctor can discuss with you the risks and benefits involved.

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

Clopidogrel/Aspirin may pass into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine if you have or have had any of the following medical conditions:

- a medical condition that causes bleeding such as a haemophilia,

- stomach ulcers or bleeding within your head or bowels
- erosive gastritis
- severe liver or kidney disease
- asthma with rhinitis and/or nasal polyps
- mastocytosis.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- bleeding disorders or blood clotting problems
- any illness or disability that was caused by bleeding, e.g. impaired sight or vision because of bleeding within the eye
- stroke
- recent serious injury
- recent surgery (including dental surgery)
- liver or kidney disease
- a genetic condition which means that a certain enzyme (CYP2C19) in your liver works differently and can negatively affect the amount of clopidogrel converting into its active form, resulting in reduced effects (your doctor may perform a test for this condition and depending on results may change your dose or consider an alternative treatment option)
- stomach ulcers or other problems with your digestive system
- inherited diseases causing galactose intolerance or glucose-galactose malabsorption

- Lapp lactase deficiency
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- gout
- asthma or allergies
- allergies to other anti-platelet medicines (such as ticlopidine or prasugrel)

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine whilst in the third trimester of pregnancy. Your doctor can discuss with you the risks and benefits involved.

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

Your doctor may advise you to go for tests to determine if this medicine will adequately work for you, as some patients may not convert this medicine to its active form.

These patients may not get the same benefit from clopidogrel/ aspirin as other patients. Based on the test results, your doctor may consider alternative treatments for you.

Taking other medicines

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

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

- aspirin and other salicylates – this medicine already contains aspirin; taking additional aspirin is not recommended unless advised by your doctor
- clopidogrel – this medicine already contains clopidogrel; taking additional clopidogrel is not recommended unless advised by your doctor

- 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, such as ibuprofen
- steroids, including hydrocortisone
- uricosuric medicines, which may be used to treat gout, such as probenecid
- methotrexate, 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
- nicorandil, used to treat chest pain (angina)
- tenofovir, an antiretroviral medicine
- varicella vaccine
- acetazolamide, used to treat glaucoma
- cimetidine, used to treat stomach ulcers
- phenytoin, diazepam, carbamazepine, oxcarbazepine and valproic acid, medicines used to treat epilepsy
- repaglinide, tolbutamide and chlorpropamide, medicines used to treat diabetes
- tamoxifen and paclitaxel, medicines used to treat breast cancer
- fluvastatin, used to lower cholesterol
- voriconazole and fluconazole, medicines used to treat fungal infections

- ciprofloxacin and chloramphenicol, antibiotic medicines
- levothyroxine, used to treat low thyroid activity
- 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
- opioids, medicines for strong pain relief, such as morphine

These medicines may be affected by clopidogrel/aspirin 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 have more information on medicines to be careful with or avoid while taking this medicine.

Alcohol consumption

The consumption of alcohol may affect how well this medicine works. It may increase blood loss and stomach irritation. Please ask your doctor for more information.

How to take this medicine

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

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

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.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

Take clopidogrel/aspirin during or immediately after a meal.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It 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.

If you forget to take it

If it is almost time to take 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 (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that 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 taking this medicine

Things you must do

Keep all your doctor's appointments so that your progress can be checked.

Take this medicine exactly as your doctor has prescribed and have any blood tests ordered by your doctor promptly.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery (including dental procedures), tell the surgeon or anaesthetist that you are taking this medicine.

This medicine may increase the risk of bleeding during an operation or dental procedure. Therefore, treatment may need to be stopped before surgery. Your doctor will decide whether to stop this medicine, and for how long.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

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

It may interfere with the results of some tests.

Tell your doctor if you are injured while taking this medicine.

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.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without 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.

Side effects

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- diarrhoea
- itching
- pain or stiffness in the joints
- ringing in the ears
- taste disturbances
- trembling
- flushing
- a fast, pounding heart beat

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

- bloody or black tar-like bowel motions
- diarrhoea with blood, mucus, stomach pain and fever
- abdominal 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
- breast enlargement in men
- 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 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
- itching, inflamed, cracking or red skin
- tightness of the chest
- yellowing of the skin or the whites of the eyes, pale stools and dark urine with vomiting and stomach pain
- oedema (build-up of fluid in the body that can cause swelling)
- low-blood sugar levels, sweating, fainting, light-headedness, weakness and fatigue – these are the symptoms of insulin autoimmune syndrome
- symptoms of an allergic reaction including 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people.

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

Product description

What it looks like

75mg/75mg tablets

Yellow, oval, biconvex coated tablet. Engraved "75-75" on one side, "APO" on the other side. AUST R 201680. AUST R 201684.

Available in blister packs of 2, 4, 7, 14, 28, 30, 50, 56, and 84 tablets or bottles of 280 tablets.

75mg/100mg tablets

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

AUST R 190326. AUST R 190325.

Available in blister packs of 2, 4, 7, 14, 28, 30, 50, 56, 84, 98, 100, 112, 280 tablets or bottles of 280 tablets.

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

Ingredients

Each tablet contains 75mg of clopidogrel (as clopidogrel hydrogen sulfate) and 75mg or 100mg of aspirin as the active ingredients.

It also contains the following inactive ingredients:

- lactose
- methylcellulose
- crospovidone
- colloidal anhydrous silica

- zinc stearate
- microcrystalline cellulose
- maize starch
- iron oxide yellow
- hypromellose
- hyprolose
- macrogol 8000
- titanium dioxide
- iron oxide red (75/100mg strength only)

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

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

Australia

Tel: (02) 8877 8333

Web: www1.apotex.com/au

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was last updated in November 2020.