

## 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.

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. 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](http://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. 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.

You may have been prescribed clopidogrel because you have

- previously suffered a heart attack or stroke, or have a condition known as peripheral arterial disease (leg pain on walking or at rest).
- suffered acute coronary syndrome (either a severe type of chest pain called unstable angina, or a heart attack). In this case you may also be prescribed aspirin.

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

Clopidogrel 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.

#### Before you take this medicine

##### When you must not take it

**Do not take this medicine if:**

- **You have or have had any of the following:**
  - a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head
  - severe liver disease
- **You are breast-feeding or intend to breast-feed. Clopidogrel may pass into human breast milk.**
- **You are hypersensitive to, or 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: 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 hay fever-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.**
- **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.

##### 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 the 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 and can negatively effect 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.
  - allergy to other antiplatelet medicines (such as ticlopidine, prasugrel).
3. You are currently pregnant or you plan to become pregnant. It is recommended that clopidogrel is not taken during pregnancy. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding, clopidogrel may pass into human breast milk.
5. You have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery (including dental surgery) or an anaesthetic. Your

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

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. These include:

- medicines used to treat or prevent blood clots, for example: aspirin, heparins, warfarin, ticlopidine and prasugrel. There may also be others.
- non-steroidal anti-inflammatory drugs (NSAIDs), used to treat arthritis, period pain, inflammation, aches and pain
- medicines used to treat stomach ulcers or reflux disease (also called heartburn)
- phenytoin, a medicine used to treat epilepsy
- tolbutamide and repaglinide, a medicine used to treat diabetes
- tamoxifen or paclitaxel, a medicine used to treat breast cancer
- fluvastatin, a medicine used to lower cholesterol
- proton pump inhibitors, medicines used to prevent gastric reflux such as omeprazole
- medicines which may affect the liver enzyme in your body which makes clopidogrel work, including: fluvoxamine, fluoxetine, moclobemide, voriconazole, fluconazole, ticlopidine, ciprofloxacin, cimetidine, carbamazepine, oxcarbazepine and chloramphenicol.

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 carefully all directions given to you by your doctor. Their instructions 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 will tell you how much of this medicine you will need to take. This will depend on your condition and whether or not you are taking any other medicines.

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

If you have acute coronary syndrome, you may receive a single starting dose of 300 mg (four 75 mg tablets) and then continue at one 75 mg tablet daily.

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

##### How to take it

Swallow the tablet with a glass of water. Do not crush or chew the tablets.

### When to take it

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 of the week. When you have taken all doses in this pack, take your next prescription in the same way.

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.

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 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 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 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.**

If you take too much clopidogrel, you may experience excessive bleeding (see 'Possible side effects' section).

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### While you are taking this medicine

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#### Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant, it is recommended you do not take clopidogrel whilst pregnant
- you are breastfeeding or are planning to breast-feed, you must not take clopidogrel whilst breastfeeding
- you are about to have any blood tests
- you are going to have surgery (including dental work) or an anaesthetic or are going into hospital. Clopidogrel may increase the risk of bleeding during an operation or some dental work.

Take clopidogrel exactly as your doctor prescribed. 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.

### 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.

### 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)

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

### 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 tells you to.
- Stop taking your medicine, or change the dosage, without first 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.

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### Possible side effects

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

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

### 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 eyes
- 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
- numbness (paralysis) or problems with co-ordination
- nausea or vomiting
- headache (severe and continuing)
- faintness or dizziness
- light-headedness or blurred vision
- slurred speech or other difficulty in speaking
- confusion or hallucinations
- fever or other signs of infection, such as a 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.

These may be serious side effects and you may need urgent medical attention

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

### Allergic reactions

**If you think you are having an allergic reaction to clopidogrel, 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, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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### Storage and Disposal

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#### 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 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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### **Product description**

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#### *What APO-Clopidogrel looks like*

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

Blister packs of 28 tablets.

Bottles of 28, 100, 500 & 1000 tablets.

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

#### *Ingredients*

Each tablet contains 75 mg of clopidogrel.

It also contains the following inactive ingredients:

- 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 198523.
- APO-Clopidogrel 75 mg tablets (bottle): AUST R 221806.

#### *Sponsor*

Apotex Pty Ltd  
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This leaflet was prepared in:

May 2017