

Clopidogrel Apotex Tablets

Contains the active ingredient clopidogrel (as besilate)

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 taking 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 the medicine.

You may need to read it again.

What this medicine is used for

Clopidogrel Apotex contains the active ingredient clopidogrel (as besilate).

Clopidogrel belongs to a group of medicines known as antiplatelet medicines.

Antiplatelet medicines prevent the clumping of very small blood cells (platelets) to reduce the chances of blood clots forming.

Clopidogrel is used to prevent blood clots forming in hardened blood vessels as they 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, 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.

There is no evidence that this medicine is addictive.

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

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 an allergy to:

- any medicine containing clopidogrel
- other antiplatelet medicines (such as ticlopidine or prasugrel)
- 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 have any of the following:

- medical conditions that cause bleeding such as a stomach ulcer or bleeding within your head
- severe liver disease

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

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

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
- recent serious injury

- recent surgery (including dental surgery)
- liver or severe kidney problems
- 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)
- rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption

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

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are planning to have an operation (including dental surgery).

Your doctor will decide whether 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 get without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines may interact with clopidogrel. These include:

- medicines used to treat or prevent blood clots e.g. aspirin, heparins, warfarin, ticlopidine and prasugrel
- non-steroidal anti-inflammatory drugs (NSAIDs), used to treat arthritis, period pain, inflammation, aches and pain
- medicines used to treat stomach ulcers, reflux disease (also called heartburn) or prevent gastric reflux e.g. proton-pump inhibitors (such as omeprazole) or cimetidine
- some medicines used to treat infections e.g. ciprofloxacin, chloramphenicol, fluconazole and voriconazole
- medicines used to treat epilepsy e.g. phenytoin, carbamazepine and oxcarbazepine
- some antidepressants e.g. fluoxetine, fluvoxamine and moclobemide
- some medicines used to treat diabetes e.g. tolbutamide and repaglinide
- tamoxifen or paclitaxel, used to treat breast cancer
- fluvastatin, used to lower cholesterol
- certain type of pain relief medicines called opiates

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 have more information on medicines to be careful with or avoid while taking this medicine.

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 instructions on the label, ask your doctor or pharmacist for help.

How much to take

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.

How to take it

Swallow the tablet with a glass of water.

Do not crush or chew the tablets.

When to take it

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.

It does not matter if you take this medicine before or after food.

How long to take it for

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

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.

If you take too much clopidogrel, you may experience excessive bleeding.

While you are taking this medicine

Things you must do

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, tell the surgeon or anaesthetist that you are taking this medicine.

Clopidogrel may increase the risk of bleeding during an operation or some dental work. It may also affect other medicines used during surgery.

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.

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

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

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

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

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 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.

Be careful when drinking alcohol while you are taking this medicine.

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.

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

- diarrhoea
- itching
- pain or stiffness in the joints
- things taste different
- flushing
- a fast, pounding heart beat

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible 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
- breast enlargement in men

- 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

- symptoms of low blood sugar (hypoglycaemia), including hunger, trembling, feeling weak

The above list includes serious side effects that may require medical attention.

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

- 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

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.

Some of these side effects, such as changes in your blood count, can only be found when your doctor does tests from time to time to check your progress.

Storage and Disposal

Storage

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

Do not store this 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 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 Clopidogrel Apotex looks like

Clopidogrel 75 mg tablets

Pink coloured, round biconvex film coated with a smooth surface. AUST R 162329.

Available in blister packs of 28 tablets.

Ingredients

Each tablet contains 75 mg of clopidogrel hydrogen sulfate.

It also contains the following inactive ingredients:

- mannitol
- microcrystalline cellulose
- colloidal anhydrous silica
- stearic acid
- hypromellose
- titanium dioxide
- iron oxide red

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Distributor

Apotex Pty Ltd

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