

CLOPIDOGREL AMNEAL TABLETS

clopidogrel (as besilate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CLOPIDOGREL AMNEAL.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CLOPIDOGREL AMNEAL against the benefits they expect it will have for you.

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

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

What CLOPIDOGREL AMNEAL is used for

CLOPIDOGREL AMNEAL belongs to a group of medicines called antiplatelet 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).

CLOPIDOGREL AMNEAL 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 AMNEAL to help

prevent blood clots forming and to reduce the risk of stroke, heart attack and 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).**
- **You have 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.**

Your doctor may have prescribed this medicine for another use. If you want more information, ask your doctor.

CLOPIDOGREL AMNEAL is only available on a doctor's prescription.

Before you take CLOPIDOGREL AMNEAL

When you must not take it

You should not take CLOPIDOGREL AMNEAL if:

- **you are allergic to clopidogrel or any of the ingredients listed under 'Product Description' at the end of this leaflet.**
- **you have a medical condition that is causing bleeding such as a stomach ulcer or bleeding within your head.**
- **you suffer from severe liver disease.**
- **you are breast feeding or intend to breast feed.**
CLOPIDOGREL AMNEAL passes into breast milk and,

therefore, there is the possibility that the breast fed baby may be affected.

- **the packaging shows signs of tampering.**
- **the expiry date on the pack has passed. If you use this product after the expiry date has passed, it may not work.**

Do not take CLOPIDOGREL AMNEAL to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

CLOPIDOGREL AMNEAL is not recommended for children as its safety and effectiveness in children have not been established.

Before you start to take it

You must tell your doctor if:

- you have allergies to any other medicines, foods, preservatives or dyes.
- you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of taking CLOPIDOGREL AMNEAL during pregnancy.
- 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 AMNEAL prior to surgery.
- if 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

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

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 store.

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

- **medicines that "thin the blood". The most common examples of these include aspirin, heparins and warfarin. There are others so please check with your doctor.**
- **non-steroidal anti-inflammatory drugs (NSAIDs) -medicines used to treat arthritis, period pain, aches and pains.**
- **medicines used to treat stomach ulcers or reflux disease (also called heartburn)**
- **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.**

These medicines may be affected by CLOPIDOGREL AMNEAL or affect how well CLOPIDOGREL AMNEAL works.

You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CLOPIDOGREL AMNEAL.

How to take CLOPIDOGREL AMNEAL

How to take it

Your doctor will tell you how many tablets to take each day.

Take CLOPIDOGREL AMNEAL only as prescribed by your doctor and follow his or her directions carefully. They may differ from the information contained in this leaflet.

The usual dose of CLOPIDOGREL AMNEAL is one 75 mg tablet daily.

Your doctor may have prescribed a different dose.

If you are prescribed CLOPIDOGREL AMNEAL for the treatment of Acute Coronary Syndrome, you will receive a starting dose of four 75 mg tablets, then one 75 mg tablet daily.

You can take CLOPIDOGREL AMNEAL before or after meals. You should swallow the tablet with a glass of water.

Take CLOPIDOGREL AMNEAL at about the same time each day. Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it.

You should take CLOPIDOGREL AMNEAL for as long as your doctor continues to prescribe it.

If you forget to take CLOPIDOGREL AMNEAL

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

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), or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much CLOPIDOGREL AMNEAL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking CLOPIDOGREL AMNEAL

Things you must do

- **Take CLOPIDOGREL AMNEAL exactly as your doctor has prescribed, and have any blood tests promptly if your doctor orders them.**
- **Tell your doctor if you become pregnant while taking CLOPIDOGREL AMNEAL.**
- **Tell your doctor if you decide to breast feed your baby. Your doctor may want to discuss this and change your medicine.**
- **Tell your doctor that you are taking CLOPIDOGREL AMNEAL if you are about to start on any new medicine.**
- **Tell all your doctors, dentists, nurses and pharmacists that you are taking CLOPIDOGREL AMNEAL.**
- **CLOPIDOGREL AMNEAL 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 AMNEAL and if so, how long before surgery or dental work.

- **Ask your doctor whether there are any activities you should avoid while taking CLOPIDOGREL AMNEAL, 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 AMNEAL.** It may take longer than usual to stop bleeding while you are taking CLOPIDOGREL AMNEAL.
- **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)

Do not suddenly stop taking CLOPIDOGREL AMNEAL without telling your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how CLOPIDOGREL AMNEAL affects you.

As with other medicines, CLOPIDOGREL AMNEAL may cause faintness or dizziness in some people. Make sure you know how you react to CLOPIDOGREL AMNEAL 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

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

Like other medicines CLOPIDOGREL AMNEAL can cause some side effects. Most are likely to be minor and temporary. However, some may be serious and need medical attention.

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
- things taste different.

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

(NOTE: If you take both CLOPIDOGREL AMNEAL 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
- 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 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
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

These could be more serious side effects - you may need urgent medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of side effects. Most people do not experience any of them.

After using CLOPIDOGREL AMNEAL

Storage

Keep CLOPIDOGREL AMNEAL 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.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of their packaging they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store CLOPIDOGREL AMNEAL or any other medicine in the bathroom or near a sink.

Do not leave CLOPIDOGREL AMNEAL in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking CLOPIDOGREL AMNEAL, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

CLOPIDOGREL AMNEAL comes as pink round biconvex film-coated tablet with “II” on one side.

Available in blister and bottles packs containing 28 tablets.

Ingredients

The active ingredient in CLOPIDOGREL AMNEAL is clopidogrel besilate. Each tablet contains 75 mg clopidogrel.

The tablet also contains:

- lactose anhydrous
- microcrystalline cellulose
- crospovidone
- glyceryl behenate
- talc
- polyvinyl alcohol
- titanium dioxide
- macrogol 3350
- lecithin
- iron oxide red

Sponsor

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141
Australia

Australian registration numbers:

CLOPIDOGREL AMNEAL
(Blister) - AUST R 204439

CLOPIDOGREL AMNEAL
(Bottle) - AUST R 204440

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