

Plidogrel Tablets

Clopidogrel besilate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Plidogrel tablets.

It does not contain all the available information. Some of the information it contains may not apply to you.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. In deciding to give you Plidogrel, your doctor has weighed the risks of you taking Plidogrel against the expected benefits it will have for you.

Always follow the instructions that your doctor and pharmacist give you about Plidogrel tablets.

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

Please read this leaflet carefully before you start taking Plidogrel.

You may wish to keep it to read again.

What is Plidogrel used for

Plidogrel contains the medicine clopidogrel besilate. Plidogrel 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).

Plidogrel 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 Plidogrel 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.

Plidogrel is only available on a doctor's prescription.

Before you take Plidogrel

When you must not take it

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

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

Before you start to take Plidogrel

You must tell your doctor if:

- **You are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of taking Plidogrel 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 Plidogrel prior to surgery.**
- **If you have or have had any medical conditions, especially the following:**
 - bleeding disorders or blood clotting problems
 - liver or 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)

- 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)
- allergic to other antiplatelet medicines (such as ticlopidine, prasugrel)
- rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption

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

Some patients may not convert Plidogrel to its active form as well as other patients. These patients may not get the same benefit from Plidogrel. Your doctor may advise you to go for tests to determine if Plidogrel will adequately work for you. Based on the test results, your doctor may change your dose of Plidogrel or consider alternative treatments for you.

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 Plidogrel 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)
- Some medicines used to treat infections (eg ciprofloxacin, chloramphenicol, fluconazole and voriconazole)
- some antidepressant medicines
- medicines used to treat epilepsy (e.g. carbamazepine, oxcarbazepine and phenytoin)
- medicines used to treat diabetes (e.g. tolbutamide, repaglinide)
- medicines used to treat breast cancer (e.g. tamoxifen, paclitaxel)
- fluvastatin - a medicine used to lower cholesterol
- medicines used to prevent gastric reflux - proton pump inhibitors (e.g. omeprazole)
- certain types of pain relief medicines called opiates.

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

Your doctor may need to change the amount of your medicines, or you may need to take different medicines.

If you are unsure about any medicine you are taking you should check with your doctor or pharmacist. They will have more information on medicines to be careful with or avoid while taking Plidogrel.

How to take Plidogrel

How to take it

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

Take Plidogrel 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 Plidogrel is one 75 mg tablet daily.

If you are prescribed Plidogrel for the treatment of Acute Coronary Syndrome, you may receive a starting dose of 300 mg (four 75 mg tablets), then one 75 mg tablet daily.

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

Take Plidogrel 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 Plidogrel for as long as your doctor continues to prescribe it.

If you forget to take it

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

While you are taking Plidogrel

Things you must do

- **Take Plidogrel 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 Plidogrel.**
- **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 Plidogrel if you are about to start on any new medicine.**
- **Tell all your doctors, dentists, nurses and pharmacists that you are taking Plidogrel. Plidogrel 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 Plidogrel and if so, how long before surgery or dental work.

- **Ask your doctor whether there are any activities you should avoid while taking Plidogrel, 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 Plidogrel.**
It may take longer than usual to stop bleeding while you are taking Plidogrel.
- **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 Plidogrel without telling your doctor.

Things to be careful of

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

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

Like other medicines Plidogrel 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
- hunger
- trembling
- flushing
- a fast, pounding heart beat

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

(NOTE: If you take both Plidogrel 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
- 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
- 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 Plidogrel

Storage

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

If you take your tablets out of the box or blister pack they will not keep well.

Keep Plidogrel in a cool, dry place where the temperature stays below 25°C.

Heat and dampness can destroy some medicines. Do not leave Plidogrel in the car on hot days.

Do not store Plidogrel or any other medication in the bathroom or near a sink.

Keep Plidogrel where young children cannot reach it.

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Plidogrel 75mg tablets come as pink round tablets.

AUST R 218326

A box contains 28 tablets.

Active Ingredient:

clopidogrel 75 mg

Other Ingredients:

- mannitol
- polyethylene glycol monomethyl ether
- microcrystalline cellulose
- hypromellose
- crospovidone
- citric acid monohydrate
- stearic acid
- talc

Opadry II pink 32K14834 which contains

- Hypromellose
- iron oxide red (E 172)
- lactose monohydrate
- glycerol triacetate
- titanium dioxide (E 171).

Supplier

Plidogrel is supplied in Australia by:

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

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