

## Clopidogrel Sandoz®

*clopidogrel hydrogen sulfate film-coated tablets*

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Clopidogrel Sandoz.

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 Clopidogrel Sandoz is used for

This medicine is used to reduce blood clots forming and to reduce the risk of heart attack, stroke or death in patients who have previously suffered a heart attack, stroke or have a condition known as peripheral arterial disease (leg pain when walking or at rest).

This medicine contains the active ingredient clopidogrel. Clopidogrel belongs to a group of medicines called anti-platelet medicines.

It works by preventing blood clots to form in hardened blood vessels. This process is called atherothrombosis and can lead to events such as stroke, heart attack or death.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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

#### Before you take Clopidogrel Sandoz

##### *When you must not take it*

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

- clopidogrel, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under 'Product description'.

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 or have had:**

- severe liver disease
- a medical condition that is causing bleeding such as stomach ulcer or bleeding within your head.

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Clopidogrel Sandoz passes into breast milk and there is a possibility that your baby may be affected.

**Do not give this medicine to a child under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established.

**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 such as impaired sight or vision because of bleeding within the eye
- recent serious injury
- recent surgery (including dental surgery)
- liver or kidney problems
- allergic to other antiplatelet medicines (such as ticlopidine, prasugrel).

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

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) in the next two weeks.**

Your doctor will decide whether or not you need to stop taking your medicine prior to surgery.

**If you have not told your doctor about any of the above, tell him/her before you start taking Clopidogrel Sandoz.**

**Some patients may not convert clopidogrel to its active form as well as other patients. These patients may not get the same benefit from clopidogrel. Your doctor may advise you to go for tests to determine if clopidogrel will adequately work for you. Based on the test results, your doctor may change your dose of clopidogrel 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 get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and Clopidogrel Sandoz may interfere with each other. These include:

- medicines that thin the blood such as aspirin, heparins and warfarin. There are others, so please check with your doctor.
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen which are used to relieve pain, swelling and other symptoms of inflammation, including arthritis, period pain, aches and pains.
- medicines used to treat or prevent stomach ulcers or reflux disease (also called heartburn)
- some medicines used to treat infections (e.g. ciprofloxacin, chloramphenicol, fluconazole and voriconazole)
- some antidepressant medicines

- medicines used to treat epilepsy (e.g. carbamazepine, oxcarbazepine and phenytoin)
- medicines used to treat breast cancer (e.g. tamoxifen, paclitaxel)
- medicines used to treat diabetes (e.g. tolbutamide, repaglinide)
- fluvastatin - a medicine used to lower cholesterol
- medicines used to prevent gastric reflux - proton pump inhibitors (e.g. omeprazole)
- certain type of pain relief medicines called opiates.

These medicines may be affected by Clopidogrel Sandoz 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 Clopidogrel Sandoz

**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, ask your doctor or pharmacist for help.**

##### *How much to take*

The standard dose for this medicine is one 75 mg tablet daily.

If you are prescribed Clopidogrel Sandoz tablets 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.

Your doctor may have prescribed a different dose.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Clopidogrel Sandoz may not work as well and your problem may not improve.

##### *How and when to take Clopidogrel Sandoz*

**Swallow the tablets whole with a glass of water before or after meals.**

**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 Clopidogrel Sandoz*

**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*

Take your dose as soon as you remember, and continue to take it as you would normally.

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

**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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 Clopidogrel Sandoz. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention.

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While you are taking Clopidogrel Sandoz

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*Things you must do*

Take your medicine exactly as prescribed by your doctor and have any blood tests done promptly if your doctor orders them.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you decide to breast feed your baby. Your doctor may want to discuss this and change your medicine.

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

Tell any other doctors, dentists, nurses and pharmacists who treat you that you are taking this medicine. This medicine 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 Sandoz and if so, how long before surgery or dental work.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Ask your doctor whether there are any activities such as certain sports that you should avoid while taking Clopidogrel Sandoz.

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 Sandoz.

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

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).

*Things you must not do*

**Do not take Clopidogrel Sandoz 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 without checking with your doctor.**

*Things to be careful of*

**Be careful driving or operating machinery until you know how this medicine affects you.**

As with other medicines, Clopidogrel Sandoz may cause faintness or dizziness in some people. Make sure you know how you react to this 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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Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Clopidogrel Sandoz.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**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 or pharmacist 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

These are mild side effects of the medicine.

**Tell your doctor as soon as possible if you notice any of the following:**

- itching, inflamed, cracking or red skin, rash or hives
- bloody or black bowel motions
- diarrhoea with blood, mucus, stomach pain and fever
- red or purple spots visible through your skin
- chest pain
- abdominal or stomach pain
- bleeding (including nose bleeds) or bruising more easily than normal
- unusually heavy or unexpected menstrual bleeding
- breast enlargement in men
- nausea or vomiting
- faintness or dizziness
- 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).

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:**

- 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
- numbness (paralysis) or problems with co-ordination
- light-headedness or blurred vision
- slurred speech or other difficulty in speaking
- severe and continuing headache
- confusion or hallucination
- 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.

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 else that is making you feel unwell.**

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

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After taking Clopidogrel Sandoz

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*Storage*

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Clopidogrel Sandoz 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.

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Product description

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*What it looks like*

Clopidogrel Sandoz 75 mg - Pink coloured film-coated round shaped tablets with SZ/75 imprinted on one side and plain on the other side.

Available in blisters of 28 tablets.

## *Ingredients*

Active ingredient:

- Clopidogrel Sandoz 75 mg - 97.875 mg clopidogrel hydrogen sulfate (equivalent to 75 mg clopidogrel).

Inactive ingredients:

- mannitol
- microcrystalline cellulose
- hyperlose
- hydrogenated vegetable oil
- Opadry Pink 03B54942
- Opacode S-1-27794 Black.

This medicine does not contain lactose, sucrose or gluten.

## *Suppliers*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park NSW 2113  
Australia  
Tel: 1800 726 369

Novartis New Zealand Ltd  
PO Box 99102, Newmarket  
Auckland 1149  
New Zealand  
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### **Australian Register Number**

75mg film-coated tablet: AUST R 155046