

Approved Patient Information Leaflet for Medicines for Human Use:

CLOPIDOGREL 75 mg AUSTELL film-coated tablets

SCHEDULING STATUS: S3

CLOPIDOGREL 75 mg AUSTELL film-coated tablets

Clopidogrel bisulphate

Contains sugar: lactose anhydrous 78,14 mg

Read all of this leaflet carefully before you start taking CLOPIDOGREL AUSTELL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CLOPIDOGREL AUSTELL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CLOPIDOGREL AUSTELL is and what it is used for
2. What you need to know before you take CLOPIDOGREL AUSTELL
3. How to take CLOPIDOGREL AUSTELL
4. Possible side effects
5. How to store CLOPIDOGREL AUSTELL
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1. What CLOPIDOGREL AUSTELL is and what it is used for

CLOPIDOGREL AUSTELL contains a medicine called clopidogrel which belongs to a group

Austell Pharmaceuticals (Pty) Ltd, 490442, CLOPIDOGREL 75 mg AUSTELL, Film-coated tablets

of medicines called “antiplatelet anticoagulants”. Platelets are small structures in the blood which clump together to form clots.

CLOPIDOGREL AUSTELL is used:

- to lessen the chance of heart attack or stroke. It is given to adults who have already had a heart attack or stroke or to those with other blood circulation problems, (including hardening of the arteries) that could lead to a stroke or heart attack,
- if you have experienced a severe type of chest pain known as ‘unstable angina’ or ‘myocardial infarction’ (heart attack). For the treatment of this condition your doctor may have placed a stent in the blocked or narrowed artery (blood vessel) to restore effective blood flow. You may also be given acetylsalicylic acid (aspirin-to prevent blood clotting) by your doctor.

A heart attack or stroke may occur when a blood vessel in the heart or brain is blocked by a blood clot. CLOPIDOGREL AUSTELL reduces the chance that a harmful blood clot will form by preventing certain cells in the blood from clumping together.

2. What you need to know before you take CLOPIDOGREL AUSTELL

Do not take CLOPIDOGREL AUSTELL

- if you are hypersensitive (allergic) to clopidogrel or any of the other ingredients of CLOPIDOGREL AUSTELL,(listed in section 6).
- CLOPIDOGREL AUSTELL is not to be used in children under the age 18.
- If you are pregnant or breastfeeding,
- if you have bleeding problems a (such as a bleeding stomach ulcer or increased bleeding tendencies that characterise platelet dysfunction),
- if you suffer from severe liver disease,
- if you have been diagnosed with haemophilia (a medical condition in which the ability of the blood to clot is severely reduced, causing you to bleed severely from

even a slight injury), either hereditary or as a result of previously taking this medicine.

If you uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking CLOPIDOGREL AUSTELL.

Warnings and precautions

Take special care with CLOPIDOGREL AUSTELL

If you have a risk of bleeding such as

- medical condition that puts you at risk of internal bleeding (such as a stomach ulcer),
- a blood disorder that makes you prone to internal bleeding (bleeding inside any tissues, organs or joints of your body),
- a recent serious injury,
- a recent surgery (including dental),
- a planned surgery (including dental) in the next seven days,
- if you have had a clot in an artery of your brain (ischemic stroke) which occurred within the last seven days,
- if you have kidney or liver disease,
- if you have had an allergy or reaction to any medicine used to treat your disease,
- if you had a past medical history of non-traumatic brain hemorrhage
- if you develop a medical condition (also known as Thrombotic Thrombocytopenic Purpura or TTP) that includes fever and bruising under the skin that may appear as red pinpoint dots, with or without unexplained extreme tiredness, confusion, yellowing of the skin or eyes (jaundice) (see section 4 “Possible side effects”)
- if you develop a condition called acquired haemophilia (causing you to bleed severely from even a slight injury) your doctor may discontinue the medicine,
- if you hypersensitive (allergic) to other anti-platelet medicines called thienopyridine (such as ticlopidine, prasugel), used to prevent blood clots.

While you are taking CLOPIDOGREL AUSTELL you may notice that cuts or injuries take a longer time to stop bleeding. This is because your medications stop clotting. For minor injuries such as cutting yourself while shaving, this is of no concern. However, inform your doctor immediately if you are concerned about your bleeding. Your doctor may need to do some blood tests.

Other medicines and CLOPIDOGREL AUSTELL

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines including medicines obtained without a prescription.

- aspirin
- non-steroidal anti-inflammatory agents (these are medications used in the treatment of pain especially painful and inflamed muscles or joints),
- ticlopidine, an antiplatelet medicine,
- abciximab or eptifibatide, antiplatelet medicines known as glycoprotein IIb/IIIa inhibitors,
- selective serotonin reuptake inhibitors (such as fluoxetine or fluvoxamine), these are medicines used to treat depression,
- omeprazole or esomeprazole, medicines used to treat ulcers and heartburn,
- rosuvastatin (used to lower your cholesterol level),
- blood clotting medication such as heparin or warfarin,
- phenytoin (antiepileptic medicine),
- efavirenz, or other anti-retroviral medicines (used to treat HIV infections),

These medicines may interact with CLOPIDOGREL AUSTELL especially if you will be taking them for a long time.

CLOPIDOGREL AUSTELL with food and drink

Take CLOPIDOGREL AUSTELL tablets with a drink of water. CLOPIDOGREL AUSTELL may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking CLOPIDOGREL AUSTELL.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

Your ability to drive or operate machinery should not be affected by CLOPIDOGREL AUSTELL.

It is not always possible to predict to what extent CLOPIDOGREL AUSTELL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CLOPIDOGREL AUSTELL affects them.

CLOPIDOGREL AUSTELL contains lactose

CLOPIDOGREL AUSTELL contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **CLOPIDOGREL AUSTELL**.

3. How to take CLOPIDOGREL AUSTELL

Do not share medicines prescribed for you with any other person.

Always take CLOPIDOGREL AUSTELL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose in adults (including the elderly) is one 75 mg CLOPIDOGREL AUSTELL tablet daily. You should take your medicine at the same time each day. This will help you remember to take it daily.

Duration of administration

Your doctor will tell you how long your treatment with CLOPIDOGREL AUSTELL will last. Do not stop treatment early because if you have the impression that CLOPIDOGREL AUSTELL is too strong or too weak, tell your doctor or pharmacist.

Method of administration

CLOPIDOGREL AUSTELL tablets should be swallowed whole with water, with or without food. Do not crush or chew the tablets.

If you take more CLOPIDOGREL AUSTELL than you should

If you have taken too much CLOPIDOGREL AUSTELL you may be at risk of serious bleeding.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take CLOPIDOGREL AUSTELL

Do not take a double dose to make up for forgotten individual dose.

If you forget to take your dose of CLOPIDOGREL AUSTELL but remember within 12 hours of your usual time, take your tablet immediately then take your next tablet at the normal time. If you forget for more than 12 hours simply take the next dose at the usual time.

If you stop taking CLOPIDOGREL AUSTELL

Do not stop the treatment unless your doctor tells you so. Contact your doctor or pharmacist before stopping.

4. Possible side effects

CLOPIDOGREL AUSTELL can have side effects.

Not all side effects reported for CLOPIDOGREL AUSTELL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking CLOPIDOGREL AUSTELL, please consult your health care provider for advice.

If any of the following happens, stop taking CLOPIDOGREL AUSTELL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- having difficulty breathing, with or without swelling of the throat and face,
- shortness of breath, wheezing or trouble breathing,
- severe itching of the skin,
- fainting
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CLOPIDOGREL AUSTELL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- vomiting blood or noticing blood in the stool or passing black tarry stools (faeces).
These could be signs of bleeding in the stomach or intestines,
- haematoma (bleeding out of blood vessels, unusual bleeding or bruising under the skin)
- if you have a fever (high temperature) and bruising under the skin that may appear as red pinpoint dots with or without unexplained extreme tiredness, confusion or hallucination (seeing things that are not there), yellowing of the skin or eyes (jaundice).
- Hives, fever (high temperature), swollen glands that do not go away, swelling of your lips and tongue, unusual bruising or bleeding, severe fatigue or weakness, unexpected pain in the muscles, frequent infections (DRESS).
- chest pain which may radiate down the arm or up into the neck,
- fever, signs of infection or extreme tiredness. These may be due to a decrease in some blood cells,
- fever (high temperature) and sore throat with a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions,
- noticing blood in the urine,
- swelling of a joint, joint pain, joint stiffness,
- bleeding in the eye or if your eyes look “bloodshot,
- intracranial bleeding (bleeding inside the brain).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- pain in your stomach area, indigestion (dyspepsia), diarrhoea, nausea (feeling sick),
- bruising of the skin,
- frequent nose bleeds.

Less frequent side effects:

- headaches, feeling dizzy or a spinning sensation (vertigo),
- a tingling sensation or numbness especially in the hands and feet (paraesthesia),
- a rash which may or may not be itchy, hives, inflammation of the skin,
- low blood pressure,
- constipation, vomiting, flatulence (passing wind), a burning sensation in the stomach (gastritis), severe diarrhoea, stomach ulcer,
- changes in liver function tests and blood creatinine (seen on a blood test),
- fever (high temperature),
- pain in the joints and muscles,
- enlarged breasts in males,
- painful mouth, changes in the taste of food.

Side effects with frequency unknown:

- hypersensitivity reactions with chest or abdominal pain,
- persistent low blood sugar symptoms,
- insulin autoimmune syndrome (condition that causes low blood sugar that manifest in involuntary hungers, tremors, anxiety, irritability, confusion, seizures or loss of consciousness).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CLOPIDOGREL AUSTELL.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store CLOPIDOGREL AUSTELL

Store all medicines out of reach of children.

- Store in the original packaging. Keep blister packs in the carton until required for use.
- Aluminium/Aluminium blister packs: Store at or below 30 °C. Polyethylene tablet containers: Store at or below 25 °C.
- Protect from moisture.
- Do not store your medicine in the bathroom.
- Do not use CLOPIDOGREL AUSTELL after the expiry date printed on the label, container or blister.
- Return any expired or unused medicine to your pharmacist for safe disposal.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLOPIDOGREL AUSTELL contains

- The active substance is clopidogrel
- The other ingredients are-crospovidone (type A), glycerol dibehenate, lactose anhydrous, microcrystalline cellulose and talc. The tablets are film coated in Opadry

Austell Pharmaceuticals (Pty) Ltd, 490442, CLOPIDOGREL 75 mg AUSTELL, Film-coated tablets

II Pink (85G34669) which consists of iron oxide red (E172), lecithin, macrogol 3350, polyvinyl alcohol, titanium dioxide (E171) and talc.

CLOPIDOGREL 75 mg AUSTELL film-coated tablet

Each CLOPIDOGREL AUSTELL film-coated tablet contains 75 mg of clopidogrel.

What CLOPIDOGREL AUSTELL looks like and contents of the pack

CLOPIDOGREL AUSTELL 75 mg film-coated tablet

CLOPIDOGREL AUSTELL film-coated tablets are pink, round, biconvex, film-coated tablets with an "I" engraved on one side.

CLOPIDOGREL AUSTELL film-coated tablets are packed in Aluminium/Aluminium blister strips of 7 or 10 tablets, which are further packed in printed cartons in pack sizes of 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90 or 100. CLOPIDOGREL AUSTELL tablets are also packed in polyethylene tablet containers in pack sizes of 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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