

CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

CLOPIDOGREL 75 BIOTECH, clopidogrel bisulphate equivalent to 75 mg of clopidogrel, film coated
tablet

Clopidogrel

Contains sugar (7,50 mg sucrose stearate and 119,64 mg isomalt per film coated tablet).

Read all of this leaflet carefully before you start using **CLOPIDOGREL 75 BIOTECH**.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **CLOPIDOGREL 75 BIOTECH** 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 75 BIOTECH** is and what it is used for
2. What you need to know before you use **CLOPIDOGREL 75 BIOTECH**
3. How to use **CLOPIDOGREL 75 BIOTECH**
4. Possible side effects
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6. Contents of the pack and other information

1. What **CLOPIDOGREL 75 BIOTECH** is and what it is used for

Each film coated tablet contains clopidogrel bisulphate equivalent to 75 mg of clopidogrel.

CLOPIDOGREL 75 BIOTECH is an antiplatelet medicine which prevents the clumping of platelets and reduces the risk of clotting of blood.

CLOPIDOGREL 75 BIOTECH is taken to prevent blood clots (thrombi) forming in hardened blood vessels, a process known as atherothrombosis, which can lead to atherothrombotic events (such as stroke, heart attack, or death) in patients with a history of symptomatic hardening of arteries (arteriosclerosis) or with a condition known as peripheral arterial disease.

2. What you need to know before you use CLOPIDOGREL 75 BIOTECH

Do not take CLOPIDOGREL 75 BIOTECH:

- If you are allergic to clopidogrel or any of the other ingredients of CLOPIDOGREL 75 BIOTECH tablets.
- If you have a bleeding stomach ulcer or bleeding within the brain.
- If you're liver function is severely impaired.
- If you are pregnant or breastfeeding your baby.
- CLOPIDOGREL 75 BIOTECH should not be given to patients younger than 18 years of age.
- If you suffer from blood disorders such as thrombocytopenia (decreased platelets), neutropenia (decreased neutrophils) and other bleeding disorders such as haemophilia (a blood disorder in which blood doesn't clot normally).

Warnings and precautions

Take special care with CLOPIDOGREL 75 BIOTECH:

If any of the following situations apply to you, you should tell your doctor before taking CLOPIDOGREL 75 BIOTECH:

- If you have thrombotic thrombocytopenic purpura [TTP]. This is a rare disorder of the blood-coagulation system, causing extensive microscopic blood clots to form in small blood vessels throughout the body.

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- if you have a risk of bleeding such as:
 - a 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
- If you are going to have surgery, spinal or epidural anaesthesia or have dental work done. CLOPIDOGREL 75 BIOTECH may increase the risk of serious bleeding during operation or some kind of dental work. Therefore, treatment may have to be stopped about 7 days before the operation or dental work is done.
- Tell all medical doctors, dentists, nurses and pharmacists you go to that you are taking CLOPIDOGREL 75 BIOTECH.
- If you have had a clot in an artery of your brain (ischaemic stroke) which occurred in the last seven days.
- If you have kidney or liver disease.
- If you recently had a heart attack.
- If you have a genetic disorder that impairs the body's ability to make blood clots.
- If you have had previous allergic reactions to thienopyridines (such as clopidogrel, ticlopidine, prasugrel).
- If you are using any other medicines e.g., aspirin, NSAID's (ibuprofen, naproxen, diclofenac, celecoxib etc.), warfarin or SSRI's (antidepressants)

Other medicines and CLOPIDOGREL 75 BIOTECH

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

Please consult your doctor, pharmacist or other healthcare professional for advice if you are using any of the following products:

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- Non-Steroidal Anti-Inflammatory Drugs (such as aspirin, ibuprofen, indometacin, diclofenac etc.)
- Heparin or warfarin
- Thrombolytics (e.g., eminas, retevase)
- Phenytoin (antiepileptic medicine)
- Tolbutamide (medicine for type-2 diabetes)
- Tamoxifen (medicine used for breast cancer)
- Fluvastatin (medicine to treat high cholesterol)
- Omeprazole and esomeprazole (medicines used to treat stomach ulcers)
- Fluvoxamine, fluoxetine and moclobemide (medicines used to treat depression and major depressive disorders and anxiety disorders)
- Voriconazole and fluconazole (medicine used to treat fungal infections)
- Ticlopidine (medicine used to prevent blood clots)
- Ciprofloxacin (medicine used to treat infections of the skin, lungs, airways, bones and joints as well as urinary tract infections)
- Cimetidine (medicines used to treat indigestion problems and stress ulcers)
- Carbamazepine and oxcarbazepine (medicine used to manage certain types of seizures and disorders like bipolar disorder)
- Chloramphenicol (an antibiotic used to treat bacterial infections)

Taking CLOPIDOGREL 75 BIOTECH with food or drink:

CLOPIDOGREL 75 BIOTECH may be taken with or without food.

Pregnancy and breastfeeding:

You should not take CLOPIDOGREL 75 BIOTECH if you are pregnant or breastfeeding.

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 healthcare provider for advice before taking CLOPIDOGREL 75

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BIOTECH.

Driving and using machines:

It is not always possible to predict to what extent CLOPIDOGREL 75 BIOTECH 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 75 BIOTECH affects them.

CLOPIDOGREL 75 BIOTECH contains sucrose stearate and isomalt:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use CLOPIDOGREL 75 BIOTECH

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

Always take CLOPIDOGREL 75 BIOTECH exactly as your doctor has instructed you. You should check with your doctor if you are unsure

The usual adult dosage is one CLOPIDOGREL 75 BIOTECH tablet daily, with or without food.

Your doctor will tell you how long your treatment with CLOPIDOGREL 75 BIOTECH will last. If you have the impression that the effect of CLOPIDOGREL 75 BIOTECH is too strong or too weak, talk to your doctor or pharmacist.

If you take more CLOPIDOGREL 75 BIOTECH than you should:

In the event of overdose, 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.

If you forget to take CLOPIDOGREL 75 BIOTECH:

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If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

4. Possible side effects

CLOPIDOGREL 75 BIOTECH can have side effects. They may need medical attention.

Not all side effects reported for CLOPIDOGREL 75 BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLOPIDOGREL 75 BIOTECH, please consult your health care provider for advice.

The most frequent side effect reported with clopidogrel as in CLOPIDOGREL 75 BIOTECH is bleeding.

Tell your doctor immediately if you have any signs or symptoms of bleeding,

- Unexpected, spontaneous bleeding or bleeding that lasts a long time;
- blood in your urine;
- red or black tarry stools;
- bruises that happen without a cause or get larger;
- nose or eye bleeding;
- respiratory bleeding;
- gastrointestinal bleeding;
- retroperitoneal bleeding;
- cough up blood or blood clots;
- vomit blood or your vomit looks like coffee grounds;
- sudden weakness.

If any of the following happens, stop using CLOPIDOGREL 75 BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in

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swallowing or breathing,

- elevated body temperature,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOPIDOGREL 75 BIOTECH. 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:

- severe skin reaction including blistering, flaking, or peeling of skin. A skin rash which itches intensely,
- bullous dermatitis (toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme),
- urticaria (an outbreak of swollen, pale red bumps or plaques (wheals) on the skin that appear suddenly),
- acute generalised exanthematous pustulosis (AGEP) (a skin condition, mainly small non-follicular pustules, caused by medication administration),
- drug rash with eosinophilia and systemic symptoms (DRESS) (extensive skin rash with visceral organ involvement, lymphadenopathy, eosinophilia, and atypical lymphocytosis),
- stomach pain (severe), stomach ulcer,
- pancreatitis (inflammation of the pancreas), colitis (inflammation of the lining of the colon and the rectum), stomatitis (inflammation of the mucous membrane of the mouth),
- irregular heartbeat, abnormally low blood pressure, inflammation of blood vessels,
- inflammation of the liver, liver failure, urinary tract infection,
- inflammation of the tiny filters in the kidney (glomerulonephritis),
- elevated creatinine levels (usually because the kidneys are not working properly),
- chest pain and upper respiratory infection,

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- low platelet count (platelets help stop bleeding),
- low white cell count (sometimes severe),
- low eosinophil count (disease-fighting white blood cells),
- high blood pressure,
- low counts for all three types of blood cells: red blood cells, white blood cells, and platelets,
- low granulocyte count,
- anaemia (lack of blood),
- aplastic anaemia (rare condition in which the body stops producing enough new blood cells),
- thrombotic thrombocytopenic purpura (TTP) (blood clots form in small blood vessels throughout the body),
- serum sickness (immune response to antigens (proteins from nonhuman sources) that's similar to an allergic reaction),
- insulin autoimmune syndrome which can lead to severe low blood sugar levels,
- Kounis syndrome (symptoms such as chest pain relating to reduced blood flow to the heart caused by an allergic reaction or a strong immune reaction to a drug or other substance),
- interstitial pneumonitis (a group of disorders that cause progressive scarring of lung tissue),

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:

- Red or purple spots on skin, varying in size from pinpoint to large bruises,
- diarrhoea, indigestion, and flatulence,
- bleeding at injection site,
- generalized pain,

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Less frequent side effects:

- chills, or sore throat, headache (sudden, severe),
- ulcers, sores, or white spots in mouth,
- dizziness, vertigo, sensation of tingling and numbness, sleeplessness,
- hallucinations, confusion, anxiety and mental depression,
- change in taste of food,
- loss of appetite, fatigue, mild fever, nausea and vomiting,
- constipation,
- joint pain, back pain, and muscular pain,
- arthritis (joint inflammation),
- cough and stuffy nose,
- eczema (itchy inflammation of the skin),
- gynaecomastia (swollen male breast tissue in men),
- tooth disorder,
- decreased muscle strength,
- fatigue (feeling overtired, with low energy and a strong desire to sleep).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CLOPIDOGREL 75 BIOTECH.

5. How to store Clopidogrel 75 Biotech

Clopidogrel 75 Biotech, film-coated tablets

Each film coated tablet contains clopidogrel bisulphate equivalent to 75 mg of clopidogrel.

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C.
- Keep the blisters in the outer carton until required for use.
- Do not use the tablets after the expiry date printed on the label or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLOPIDOGREL 75 BIOTECH contains

The active substance is clopidogrel bisulphate equivalent to 75 mg of clopidogrel.

The other ingredients are: hydroxypropyl cellulose, isomalt, low-substituted hydroxypropyl cellulose, Opadry 03B24440 PINK (consisting of hypromellose, red iron oxide, titanium dioxide, Macrogol 4000), purified water and sucrose stearate.

What CLOPIDOGREL 75 BIOTECH looks like and contents of the pack

CLOPIDOGREL 75 BIOTECH are pink, round, biconvex tablets.

CLOPIDOGREL 75 BIOTECH tablets are packed in silver polyamide/aluminium/ polyvinylchloride and aluminium blister strips. Each strip contains 14 tablets with 2 blister strips per outer carton.

Holder of Certificate of Registration

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1.3.2 Clean Patient Information Leaflet
Format and Safety update
04 February 2021
SAHPRA – approved 17 April 2021

Tel: (011) 848 3050

This leaflet was last revised in

04 February 2021 - SAHPRA approved 17 April 2021

Registration number

45/8.2/0327