

# CLOPIDOGREL 75 BIOTECH

## 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
5. How to store CLOPIDOGREL 75 BIOTECH
6. Contents of the pack and other information

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

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 (atherosclerosis) 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.
- 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:*

- Non-Steroidal Anti-Inflammatory Drugs (such as aspirin, ibuprofen, indometacin, diclofenac etc.)
- Heparin or warfarin
- Thrombolytics (e.g., eminas, retavase)
- 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 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 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.

#### If you forget to take CLOPIDOGREL 75 BIOTECH:

If you missed a dose, take it as soon as you remember. If it is almost time for you 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 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,
  - 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,

*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**

- 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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# CLOPIDOGREL 75 BIOTECH

## PASIENT INLICHTINGSBLAD

### SKEDULERINGSSTATUS

S3

CLOPIDOGREL 75 BIOTECH, klopidogrelbisulfaat gelykstaande aan 75 mg klopidogrel, filmbedekte tablet  
Klopidogrel  
Bevat suiker (7,50 mg sukrosetearaat en 119,64 mg isomalt per filmbedekte tablet).

### Lees hierdie hele blad noukeurig deur voordat u begin om CLOPIDOGREL 75 BIOTECH te gebruik.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- CLOPIDOGREL 75 BIOTECH is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u's'n.

### Wat in hierdie blad is

1. Wat CLOPIDOGREL 75 BIOTECH is en waarvoor dit gebruik word
2. Wat u moet weet voordat u CLOPIDOGREL 75 BIOTECH drink
3. Hoe om CLOPIDOGREL 75 BIOTECH te gebruik
4. Moontlike nuwe-effekte
5. Hoe om CLOPIDOGREL 75 BIOTECH te bêre
6. Inhoud van die pak en ander inligting

### 1. Wat CLOPIDOGREL 75 BIOTECH is en waarvoor dit gebruik word

CLOPIDOGREL 75 BIOTECH is 'n antiplaatjemiddel wat die saamklewing van bloedplaatjies voorkom en die risiko vir bloedklonte verlaag. CLOPIDOGREL 75 BIOTECH word gebruik om te verhoed dat bloedklonte (trombi) in verharde bloedvate vorm, 'n proses bekend as aterotrombose, wat tot aterosklerotiese voorvalle (soos 'n beroerte, hartaanval, of dood) kan lei in pasiënte met 'n geskiedenis van simptomatiese verharding van bloedvate (aterosklerose) met 'n toestand bekend as perifere arteriële siekte.

### 2. Wat u moet weet voordat u CLOPIDOGREL 75 BIOTECH drink

#### U moet CLOPIDOGREL 75 BIOTECH nie drink nie:

- as u allergies (hipersensitief) vir klopidogrel of vir enige van die ander bestanddele van CLOPIDOGREL 75 BIOTECH is.
- as u 'n bloeiende maagseer of bloeding op die brein het.
- as u leverfunksie erg aangetas is.
- as u swanger is of u baba borsvoed.
- CLOPIDOGREL 75 BIOTECH moet nie vir kinders van jonger as 18 jaar gegee word nie.
- as u aan bloedversteurings ly, soos trombositopenie (min bloedplaatjies), neutropenie (min neutrofiële) en ander bloedingsversteurings soos hemofilie ('n bloedversteuring waarin bloed nie normaal stol nie).

### Waarskuwings en voorsorgmaatreëls

#### Wees besonder versigtig met CLOPIDOGREL 75 BIOTECH:

*Indien enige van die volgende situasies op u van toepassing is, moet u vir u dokter sê as u voordat u CLOPIDOGREL 75 BIOTECH drink:*

- As u trombotiese trombositopeniese purpura [TTP] het. Dit is 'n seldsame versteuring van die bloedstollingstelsel, wat veroorsaak dat mikroskopiese bloedklonte grootskaals in klein bloedvate regdeur die liggaam vorm.
- As u 'n risiko vir bloeding het, soos:
  - 'n mediese toestand wat u in gevaar stel om inwendige bloeding te hê (soos 'n maagseer).
  - 'n bloedversteuring wat u geneig maak tot inwendige bloeding (bloeding in enige weefsel, organe of gewrigte van u liggaam).
  - 'n onlangse ernstige besering.
- As u 'n operasie moet ondergaan, spinale of epidurale verdoving of tandheelkundige werk laat doen. CLOPIDOGREL 75 BIOTECH kan die risiko vir ernstige bloeding tydens 'n operasie of een of ander soort tandheelkundige werk verhoog. Daarom moet behandeling dalk ongeveer 7 dae voor die operasie of tandheelkundige werk gestaak word.
- Sê vir alle mediese dokters, tandartse, verpleegkundiges en aptekers na wie toe u gaan dat u CLOPIDOGREL 75 BIOTECH gebruik.
- As u 'n klont in 'n slagaaier van u brein gehad het (iskemiese beroerte) wat in die afgelope sewe dae plaasgevind het.
- As u 'n nier- of lewersiekte het.
- As u onlangs 'n hartaanval gehad het.
- As u 'n genetiese afwyking het wat die liggaam se vermoë om bloedklonte te maak, benadeel.
- As u voorheen allergiese reaksies op tiënopiridien gehad het (soos klopidogrel, tiklopidien, prasugrel).
- As u enige ander medisyne gebruik, bv aspirien, NSAÏM's (ibuprofeen, naprokseen, diklofenak, selekoksib ens.), warfarien of SSHR's (antidepressante).

### Ander medisyne en CLOPIDOGREL 75 BIOTECH

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder aanvullende of tradisionele medisyne).

*Raadpleeg u dokter, apteker of ander gesondheidspraktisyn asseblief om raad as u enige van die volgende produkte gebruik:*

- Nie-steroid anti-inflammatoriese middels (soos aspirien, ibuprofeen, indometasien, diklofenak, ens.)
- Heparien of warfarien
- Trombolitika (bv. eminas, retavase)
- Fenitoïen (anti-epileptiese medisyne)
- Tolbutamied (medisyne vir tipe 2-diabetes)
- Tamoksifeen (medisyne vir borskanker)
- Fluvastatin (medisyne om hoë cholesterolvlakke te behandel)
- Omeprasool en esomeprasool (wat vir maagseer gebruik word)
- Flukoksamien, flukosetien en moklobemied (medisyne om depressie en erge depressiewe versteurings en angsversteurings te behandel)
- Vorikonasool en flukonasool (om fungusinfeksies te behandel)
- Tiklopidien (medisyne om bloedklonte te voorkom)
- Siprofloksasiën (om infeksies van die vel, longe, ligweë, bene en gewrigte sowel as urienweginfeksies te behandel)
- Simetidien (om spysverteringsprobleme en stressere te behandel)
- Karbamasepien en okskarbasepien (om sekere soorte toevalle en versteurings soos bipolêre versteuring te bestuur)
- Chlooramfenikol ('n antibiotikum om bakteriële infeksies te behandel)

### Gebruik van CLOPIDOGREL 75 BIOTECH saam met kos en drank

CLOPIDOGREL 75 BIOTECH kan met of sonder voedsel gedrink word.

### Swangerskap en borsvoeding

U moet nie CLOPIDOGREL 75 BIOTECH drink as u swanger is of borsvoed nie.

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u CLOPIDOGREL 75 BIOTECH drink.

### Motorbestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel tot watter mate CLOPIDOGREL 75 BIOTECH met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet sorg dat hulle, totdat hulle weet hoe CLOPIDOGREL 75 BIOTECH hulle beïnvloed, nie aan bogenoemde aktiwiteite deelneem nie.

### CLOPIDOGREL 75 BIOTECH bevat sukrosetearaat en isomalt

As u dokter vir u gesê het dat u 'n onverdraagbaarheid teenoor sekere suikers het, moet u u dokter skakel voordat u hierdie medisyne gebruik.

### 3. Hoe om CLOPIDOGREL 75 BIOTECH te gebruik

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Gebruik CLOPIDOGREL 75 BIOTECH altyd presies soos wat u dokter vir u gesê het. Raadpleeg u dokter as u nie seker is nie.

Die gewone volwasse dosis is een CLOPIDOGREL 75 BIOTECH-tablet daaglik, met of sonder kos.

U dokter sal vir u sê hoe lank u behandeling met CLOPIDOGREL 75 BIOTECH sal duur. Praat met u dokter of apteker as u die indruk het dat die effek van CLOPIDOGREL 75 BIOTECH te sterk of te swak is.

### As u meer CLOPIDOGREL 75 BIOTECH gedrink het as wat u moes:

Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie pamflet en die oorblywende tablette saam.

### As u vergeet om CLOPIDOGREL 75 BIOTECH te drink

As u 'n dosis oorgeslaan het, drink dit sodra as wat u onthou. As dit egter byna tyd vir u volgende dosis is, slaan die dosis wat gemis is oor en drink die tablet op die gewone tyd. Moenie 'n dubbele of groter dosis drink om vir die vergeete individuele dosis op te maak nie.

### 4. Moontlike nuwe-effekte

CLOPIDOGREL 75 BIOTECH kan nuwe-effekte hê. Mediese aandaag mag daarvoor nodig wees.

Nie al die nuwe-effekte wat vir CLOPIDOGREL 75 BIOTECH aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u enige nuwe-effekte ervaar terwyl u CLOPIDOGREL 75 BIOTECH drink, moet u u dokter, apteker of ander gesondheidsorgverskaffer om advies raadpleeg. Die mees algemene nuwe-effek wat met klopidogrel, soos in CLOPIDOGREL 75 BIOTECH, aangemeld is, is bloeding.

Sê dadelik vir u dokter as u enige tekens of simptome van bloeding opmerk.

- onverwagte, spontane bloeding of bloeding wat lank aanhou
- bloed in die uriene
- rooi of swart teeragtige stoelgang
- kneusplekke wat sonder 'n oorsaak gebeur of groter word
- neus- of oogbloeding
- respiratoriese bloeding
- gastro-intestinale bloeding
- retroperitoneale bloeding
- hoes bloed of bloedklonte op
- opbring van bloed of van materiaal wat soos gemaalde koffie lyk
- skielike swakheid

**As enige van die volgende voorkom, moet u ophou om CLOPIDOGREL 75 BIOTECH te gebruik en dadelik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:**

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- hoë liggaamstemperatuur
- veluitslag of jeuk
- floutes

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op CLOPIDOGREL 75 BIOTECH gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

**Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:**

- erge velreaksie waaronder blase, afdop of afskilfering van die vel, 'n Veluitslag wat intens jeuk,
  - blaasagtige dermatose (toksiese epidermale nekrolise, Stevens-Johnsonsindroom, multivorme eriteem)
  - urtikarie ('n uitbraak van geswelde, ligrooi knoppe of plate (strepe) wat skielik op die vel voorkom)
  - akute veralgemeende eksantematiese pustulose (AVEP) ('n veltoestand, hoofsaaklik klein nie-follikulêre pustels, veroorsaak deur medikasie)
  - geneesmiddeluitslag met eosinofilie en sistemiese simptome (GRESS) (uitgebreide veluitslag met betrokkenheid van visserale organe, limfadenopatie, eosinofilie en atipiese limfotose)
  - maagpyn (erg), maagsere
  - pankreatitis (ontsteking van die pankreas), kolitis (ontsteking van die voering van die kolon en die rektum), stomatitis (ontsteking van die slymvlies van die mond)
  - onreëlmatige hartklop, abnormaal lae bloeddruk, inflammasie van bloedvate
  - inflammasie van die lewer, lewersversaking, urieneweginfeksie
  - ontsteking van die klein filters in die niere (glomerulêre nefritis)
  - hoë kreatinienvlakke (gewoonlik omdat die niere nie behoorlik werk nie)
  - pyn in die borskas, boonstelugweginfeksie
  - lae bloedplaatjietelling (plaatjies help om bloeding te stop)
  - lae witseltelling (soms erg)
  - lae eosinofieltekening (witbloedselle wat siektes bestry)
  - hoë bloeddruk
  - lae tellings van al drie tipes bloedselle: rooibloedselle, witbloedselle en bloedplaatjies
  - lae granuloesietelling,
  - anemie (tekort aan bloed)
  - aplastiese bloedarmoede (die liggaam hou op om genoeg nuwe bloedselle te maak)
  - trombotiese trombositopeniese purpura (TTP) (bloedklonte vorm in klein bloedvate regdeur die liggaam)
  - serumsiekte (immuunrespons op antigene (proteïene van nie-menslike oorsprong) wat soortgelyk is aan 'n allergiese reaksie)
  - insulien outo-immuun sindroom wat kan lei tot erge lae bloedsuikervlakke
  - Kounis-sindroom (simptome soos pyn op die bors vanweë minder bloedvloei na die hart wat veroorsaak word deur 'n allergiese reaksie of 'n sterk immuunreaksie op 'n geneesmiddel of ander stof)
  - interstisiële pneumonitis ('n groep afwykings wat progressiewe littekens van longweefsel veroorsaak)
- Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

**Sê vir u dokter as u enige van die volgende opmerk:**

*Nuwe-effekte wat dikwels voorkom:*

- rooi of pers kolle op die vel, wat wissel in grootte van kolletjies tot groot kneusplekke
- diarree, slegte spysvertering en winderigheid
- bloeding by 'n inspuitlek
- algemene pyn

*Nuwe-effekte wat minder dikwels voorkom:*

- koue rillings, of seer keel, hoofpyn (skielik, erg)
  - maagsere, sere of wit kolle in die mond
  - duiseligheid, vertigo, tinteling en gevoelloosheid, slapeloosheid
  - hallusinasies, verwardheid, angs en depressie
  - verandering in die smaak van voedsel
  - verlies aan eetlus, moegheid, ligte koors, naarheid en braking
  - hardlywigheid
  - gewrigspyn, ruggpyn en pyn in die spiere,
  - artritis (gewrigsontsteking)
  - hoes en toe neus,
  - ekseem (jeukende ontsteking van die vel)
  - ginekomiastie (geswelde manlike borsweefsel in mans)
  - tandversteuring
  - afname in spierkrag
  - moegheid (voel oormoeg, met min energie en 'n sterk begeerte om te slaap)
- As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

**Aanmeld van nuwe-effekte**

Praat met u dokter, apteker of verpleegkundige as u nuwe-effekte kry. U kan nuwe-effekte ook by SAROGP ("SAHPRA") aanmeld met die toepasslike vorm, naamlik **"6.04 Adverse Drug Reaction Reporting Form"** wat aanlyn by SAHPRA se publikasies gekry kan word: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van CLOPIDOGREL 75 BIOTECH te gee.

**5. Hoe om CLOPIDOGREL 75 BIOTECH te bêre**

- HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Berg by of onder 25 °C.
- Hou die stulpstrokke in die karton totdat dit benodig word.
- Moenie die tablette na die vervaldatum op die etiket of stulpstrokke gebruik nie.
- Gee alle ongebruikte medisyne terug aan u apteker.
- Ongebruikte medisyne moet nie in dreinerings- of rioolstelsels (bv. toilette) weg gegooi word nie.

**6. Inhoud van die pak en ander inligting**

**Wat CLOPIDOGREL 75 BIOTECH bevat**

Die aktiewe bestanddeel is klopidoorelbisulfaat gelykstaande aan 75 mg klopidoorel.

Die ander bestanddele is hidrokisipropielmetiellselulose, isomalt, lae-gesubstitueerde hidrokisipropielselulose, Opadry 03B24440 PINK (bestaande uit hipromellose, rooi ysteroksied, titaandioksied, Makrogol 4000), gesuiwerde water en sukroesestearaat.

**Hoe CLOPIDOGREL 75 BIOTECH lyk en die inhoud van die pak**

CLOPIDOGREL 75 BIOTECH is pienk, ronde, biconvekse tablette. CLOPIDOGREL 75 BIOTECH-tablette is verpak in silwer poliamied/aluminium/polivinielchloried en aluminium stulpstrokke. Elke stulpstrokke bevat 14 tablette met 2 stulpstrokke per karton.

**Houer van die registrasiesertifikaat**

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Tel.: 011 848 3050

**Hierdie blad is laas hersien in**

04 Februarie 2021 - SAHPRA goedgekeur 17 April 2021

**Registrasienumer**

45/8.2/0327