SCHEDULING STATUS
S3

PROPRIETARY NAME (AND DOSAGE FORM)
CLOPIDOGREL 75 BIOTECH (Film coated tablet).

COMPOSITION
Each film coated tablet contains clopidogrel bisulphate equivalent to 75 mg of clopidogrel.
Excipients: Isomalt, hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, sucrose fatty acid ester (3 %), purified water, Opadry 03B24440 PINK (consisting of hypromellose, red iron oxide, titanium dioxide, Macrogol 4000).
Contains sugar.

PHARMACOLOGICAL CLASSIFICATION
A 8.2 Anticoagulants.

PHARMACOLOGICAL CLASSIFICATION
Pharmacodynamic properties
Clopidogrel is a specific inhibitor of platelet aggregation. Clopidogrel acts by selectively inhibiting adenosine diphosphate (ADP) binding to its platelet receptor, and the subsequent ADP-mediated activation of the glycoprotein GPIIb / IIIa complex, thereby inhibiting platelet aggregation.
To produce inhibition of platelet aggregation, biotransformation of clopidogrel is necessary.
Clopidogrel also inhibits platelet aggregation induced by other agonists by blocking the amplification of platelet activation by released ADP.
Clopidogrel acts by irreversibly modifying the platelet ADP receptor.
Consequently, platelets exposed to clopidogrel are affected for the remainder of their lifespan.
Platelet aggregation and bleeding time gradually return to baseline values within 7 days after treatment has been discontinued.

Pharmacokinetic properties
Clopidogrel is incompletely absorbed after oral doses. At least 50 % is absorbed. It is a prodrug and is extensively metabolised in the liver. The active metabolite appears to be a thiol derivative. Clopidogrel and the inactive carboxylic acid derivative are highly protein bound. Clopidogrel and its metabolites are excreted in urine and in faeces; about 50 % of an oral dose is recovered from the urine and about 46 % from the faeces.

INDICATIONS
Reduction of atherosclerotic events (myocardial infarction, stroke) in patients with a history of symptomatic atherosclerotic disease defined by ischemic stroke (from 7 days until less than 6 months), myocardial infraction (from a few days until less than 35 days) or established peripheral arterial disease.

CONTRA-INDICATIONS
Hypersensitivity to clopidogrel or any of the excipients of CLOPIDOGREL 75 BIOTECH.
Active bleeding such as peptic ulcer and intracranial haemorrhage.
Safety and efficacy in patients younger than 18 years have not been established.
Pregnancy and lactation.
Severe liver impairment.
Thrombocytopenia, neutropenia and other haematopoietic or haemorrhagic disorders.

WARNINGS and SPECIAL PRECAUTIONS

Thrombotic thrombocytopenic purpura (TTP) may occur with CLOPIDOGREL 75 BIOTECH, especially during the first two weeks of treatment. Prescribers should warn patients about the signs and symptoms of thrombotic thrombocytopenic purpura.

The clinical diagnosis of TTP is characterised by the presence of thrombocytopenia, haemolytic anaemia, neurological symptoms, renal dysfunction and fever. Due to the risk of a fatal outcome, CLOPIDOGREL 75 BIOTECH should be discontinued in the event of suspected TTP. Early treatment with plasmapheresis is indicated in TTP.

Clopidogrel as in CLOPIDOGREL 75 BIOTECH produces irreversible inhibition of platelet aggregation for the life of a platelet, i.e. for 7 to 10 days. Routine surgery is not recommended until a patient has been off CLOPIDOGREL 75 BIOTECH for 7 days. Spinal and epidural anaesthesia should not be administered to a patient taking CLOPIDOGREL 75 BIOTECH or for 7 days thereafter. No lumbar puncture should be done during these 7 days.

Risk of haematoma formation following lumbar puncture or spinal and epidural anaesthesia.
Risk of active bleeding such as bleeding peptic ulcer and intracranial haemorrhage.
Risk of increased blood loss during dental and surgical procedures.

CLOPIDOGREL 75 BIOTECH should be used with caution in patients receiving other medicines that increase the risk of bleeding (see "INTERACTIONS").

In patients who are poor CYP2C19 metabolisers, clopidogrel, at the recommended dose forms less of the active metabolite of clopidogrel and has a smaller effect on platelet function.

Since clopidogrel is metabolised to its active metabolite partly by CYP2C19, concomitant use of CLOPIDOGREL 75 BIOTECH and strong or moderate CYP2C19 inhibitors is not recommended (see "INTERACTIONS").

In patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions, CLOPIDOGREL 75 BIOTECH should be used with caution (see "INTERACTIONS").
CLOPIDOGREL 75 BIOTECH should be discontinued 7 days prior to surgery, if a patient is to undergo elective surgery and an antiplatelet effect is not desired.

CLOPIDOGREL 75 BIOTECH prolongs bleeding time. CLOPIDOGREL 75 BIOTECH should be used with caution in patients who have lesions with a tendency to bleed (such as gastrointestinal ulcers). Medicines that might induce such lesions (such as aspirin and Non-steroidal Anti-Inflammatory Agents) should be used with caution in patients taking CLOPIDOGREL 75 BIOTECH.

Patients should be told that it may take longer than usual to stop bleeding when they take CLOPIDOGREL 75 BIOTECH and that they should report any unusual bleeding to their medical practitioner. Patients should be advised to inform medical practitioners and dentists that they are taking CLOPIDOGREL 75 BIOTECH before any surgery is scheduled and before any new medicine is taken.

Clinical experience is limited in patients with renal impairment and moderate hepatic disease that may have bleeding diatheses. CLOPIDOGREL 75 BIOTECH should therefore be used with caution in this population.
In patients with acute myocardial infarction, CLOPIDOGREL 75 BIOTECH therapy should not be initiated within the first few days following myocardial infarction.

CLOPIDOGREL 75 BIOTECH cannot be recommended in unstable angina, PTCA (stenting), CABG and acute ischaemic stroke (less than 7 days) due to a lack of data.

Effects on ability to drive and use machines
No impairment of driving or psychometric performance was observed following CLOPIDOGREL 75 BIOTECH administration.

INTERACTIONS
Concurrent use of aspirin or Non-Steroidal Anti-inflammatory Agents (NSAIDs), including COX-2 inhibitors, and CLOPIDOGREL 75 BIOTECH may increase the risk of gastrointestinal bleeding.

The safety of heparin and other thrombolytic agents (including warfarin) with CLOPIDOGREL 75 BIOTECH has not been established and concomitant use should be undertaken with caution.

CLOPIDOGREL 75 BIOTECH should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other conditions/disorders that may require concomitant glycoprotein IIb / IIIa inhibitors intake.
CYP2C19 inhibitors: Since clopidogrel is metabolised to its active metabolite partly by CYP2C19, use of medicines that inhibit the activity of this enzyme would be expected to result in reduced levels of the active metabolite of clopidogrel resulting in decreased antiplatelet activity. As a precaution, concomitant use of strong or moderate CYP2C19 inhibitors and CLOPIDOGREL 75 BIOTECH is not recommended (see WARNINGS).
Medicines products that inhibit CYP2C19 include omeprazole and esomeprazole, fluvoxamine, fluoxetine, moclobemide, voriconazole, fluconazole, ticlopidine, ciprofloxacin, cimetidine, carbamazepine, oxcarbazepine and chloramphenicol.

Other concomitant therapy: CLOPIDOGREL 75 BIOTECH could inhibit the activity of one of the Cytochrome P450 (CYP) enzymes (CYP2C9). This could lead to increase plasma levels of medicines such as phenytoin, tolbutamide, warfarin, tamoxifen, fluvastatin and many NSAIDs which are metabolised by CYP2C9.

PREGNANCY AND LACTATION
The use of CLOPIDOGREL 75 BIOTECH in pregnancy and lactation is not recommended as safety and efficacy have not been established (see CONTRA-INDICATIONS).

DOSAGE AND DIRECTIONS FOR USE
The adult dosage is a single daily dose of one tablet of CLOPIDOGREL 75 BIOTECH daily, with or without food.

SIDE EFFECTS
Bleeding is the most frequent side effect reported with clopidogrel as in CLOPIDOGREL 75 BIOTECH.

Blood and the lymphatic system disorders:
Less frequent: Thrombocytopenia (including severe thrombocytopenia), leucopenia, eosinophilia, hypertension, haematoma and eye bleeding (mainly conjunctival and intracranial bleeding), neutropenia including (severe neutropenia), agranulocytosis, pancytopenia, agranulocytopenia, anaemia, aplastic anaemia and thrombotic thrombocytopenic purpura (TTP).

Immune system disorders:
Hypersensitivity reactions, such as bronchospasm, angioedema, anaphylactoid reactions, serum sickness.

Psychiatric disorders:
Less frequent: Hallucinations, confusion, anxiety, mental depression.

Nervous system disorders:
Less frequent: Headache, dizziness, vertigo, taste disturbances, insomnia, and paraesthesia.

Cardiac disorders:
Less frequent: Atrial fibrillation or palpitations.

Vascular disorders:
Frequent: Haematoma (see blood and the lymphatic system disorders)
Less frequent: Oedema, serious haemorrhage, haemorrhage of operative wound, vasculitis, hypotension.

Respiratory, thoracic and mediastinal disorders:
Frequent: Chest pain, upper respiratory infection, epistaxis.
Less frequent: Respiratory tract bleeding (haemoptysis, pulmonary haemorrhage), bronchitis, dyspnoea, cough, rhinitis and interstitial pneumonitis.

Gastro-intestinal disorders:
Frequent: Constipation, diarrhoea and flatulence, abdominal or stomach pain, dyspepsia, gastrointestinal haemorrhage.
Less frequent: Gastritis, constipation, vomiting, nausea, peptic ulcer, loss of taste, gastric ulcer, duodenal ulcer, retroperitoneal haemorrhage (including fatal outcome), pancreatitis, colitis (including ulcerative or lymphocytic colitis), stomatitis.

Hepato-biliary disorders:
Less frequent: Acute liver failure, hepatitis, abnormal liver function test.

Skin and subcutaneous tissue disorders:
Frequent: Purpura and bruising.
Less frequent: Severe skin reactions including blistering, flaking or peeling of skin, rash, rash erythematous, bullous dermatitis (toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme) itching, urticaria, eczema, lichen planus.

Musculoskeletal, connective tissue and bone disorders:
Less frequent: Gout, arthralgia, back pain, musculoskeletal bleeding (haemarthrosis), arthritis, myalgia.

Renal and urinary disorders:
Less frequent: Haematuria, urinary tract infection, glomerulonephritis, increased blood creatinine.

General disorders and administrative site conditions:
Frequent: Bleeding at puncture site, generalised pain.
Less frequent: Syncope, tooth disorder, flu-like symptoms, fever, asthenia, and fatigue.

Investigations:
Less frequent: Prolonged bleeding time, decreased neutrophil count, decreased platelet count.

KNOWN SYMPTOMS OF OVERDOSAGES AND PARTICULARS OF ITS TREATMENT
An overdose of CLOPIDOGREL 75 BIOTECH may lead to prolonged bleeding time and subsequent bleeding complication (see SIDE EFFECTS).
Treatment is symptomatic and supportive.

IDENTIFICATION
Pink, round, biconvex tablet.

PRESENTATION
CLOPIDOGREL 75 BIOTECH tablets are packed in silver polyamide/aluminium/ polyvinylchloride and aluminium blister strips. Each carton contains 28 tablets.

STORAGE INSTRUCTIONS
Store at or below 25 °C in a dry place.
Keep the blister in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER
A45/8.4/0327

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Biotech Laboratories (Pty) Ltd.
Ground Floor, Block K West, Central Park, 400 16th Road
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DATE OF PUBLICATION OF THE PACKAGE INSERT
Date of registration: 20 April 2015

PA450327/3

SKEDULERINGSTATUS
S3

EIENDOMSNAAM (EN DOSEERVORM)
CLOPIDOGREL 75 BIOTECH (Filmbedekte tablet).

SAMESTELLING
Elke filmbedekte tablet bevat klopidogrel bisulfaat gelykstaande aan 75 mg klopidogrel.
Onaktiewe bestanddele: Isomalt, hidroksiepropiel sellulose, lae-vervangde hidroksiepropiel sellulose, sukrose vetsuur ester (3 %), gesuiwerde water, Opadry 03B24440 PINK (bestaande uit hipromellose rooi ysteroksied, titaandioksied, Macrogol 4000).
Bevat suiker.

FARMAKOLOGIESE KLASSIFIKASIE
A 8.2 Antistollingsmiddels

FARMAKOLOGIESE KLASSIFIKASIE
Farmakodinamiese eienskappe
Klopidogrel is 'n spesifieke inhibeerder van plaatjie aggregasie. Klopidogrel inhibeer die binding van adenosine-difosfaat (ADP) aan sy plaatjiereseptor, en die daaropvolgende ADP-bemiddelde aktivering van die glikoproteïen GPIIb/IIIa-kompleks, wat daardeur dus plaatjie-aggregasie inhibeer. Biotransformasie van klopidogrel is nodig om die inhibering van plaatjie aggregasie te produseer. Klopidogrel inhibeer ook plaatjie aggregasie wat deur ander agoniste geïnduseer word deur die versterking van plaatjie-aktivering deur vrygestelde ADP te blokkeer.
Klopidogrel werk deurdat dit die plaatjie-ADP-reseptor onomkeerbaar wysig.
Gevolglik word plaatjies wat aan klopidogrel blootgestel is vir die res van hul leeftyd beïnvloed. Plaatjie-aggregasie en bloedingstyd keer geleidelik terug na basiswaardes binne 7 dae na behandeling gestaak is.

Farmakokinetiese eienskappe
Clopidogrel word onvolledig geabsorbeer na orale dosisse. Ten minste 50 % is geabsorbeer. Dit is 'n progeneesmiddel en word op 'n groot skaal in die lewer gemetaboliseer. Die aktiewe metaboliet blyk om 'n -tiool derivaat te wees. Klopidogrel en die onaktiewe karboksielsuur-derivaat is hoogs proteïengebonde. Klopidogrel en sy metaboliete word in die uriene en feses uitgeskei; ongeveer 50 % van 'n orale dosis deur die uriene en 46 % deur die feses.

INDIKASIES
Vermindering van arteroskleroticse insidente (miokardiale infarksie, beroerte) in pasiënte met 'n geskiedenis van simptomatiese aterosklerotiese siekte gedefinieer deur iskemiese beroerte (van 7 dae tot minder as 6 maande), miokardiale infarksie (van 'n paar dae tot minder as 35 dae), of gevestigde perifere arteriële siekte.

KONTRA-INDIKASIES
Hipersensitiwiteit teenoor klopidogrel of enige van die bestanddele van CLOPIDOGREL 75 BIOTECH.
Aktiewe bloeding, soos b.v. peptiese ulkusse en intrakraniale bloeding.
Veiligheid en doeltreffendheid in persone jonger as 18 jaar is nog nie vasgestel nie.
Swangerskap en borsvoeding.
Erge lewerinkorting.
Trombositopenie, neutropenie en ander hematopoïetiese- of bloedingsversteurings.

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS

Trombotiese trombositopeniese purpura (TTP) mag voorkom met die gebruik van CLOPIDOGREL 75 BIOTECH, veral tydens die eerste twee weke van behandeling. Geneeshere moet pasiënte ook waarsku oor die tekens en simptome van trombotiese trombositopeniese purpura.

Die kliniese diagnose van TTP word gekarakteriseer deur die teenwoordigheid van trombositopenie, hemolitiese anemie, neurologiese simptome, nierdisfunksie en koors. As gevolg van die risiko van noodlottige uitkoms, moet die gebruik van CLOPIDOGREL 75 BIOTECH gestaak word wanneer TTP vermoed word. Vroeë behandeling met plasmaferese word aangedui in TTP.

Klopidogrel soos in CLOPIDOGREL 75 BIOTECH produseer onomkeerbare inhibering van plaatjie-aggregasie vir die leeftyd van 'n bloedplaatjie, d.w.s. vir 7 tot 10 dae. Roetine chirurgie word nie aanbeveel voordat 'n pasiënt vir 7 dae van CLOPIDOGREL 75 BIOTECH af is nie. Spinale en epidurale narkose moet nie aan 'n pasiënt gegee word terwyl CLOPIDOGREL 75 BIOTECH geneem word of vir 7 dae daarna nie. Geen lumbale punksie moet gedurende hierdie 7 dae gedoen word nie.

Risiko van hematoomvorming na 'n lumbale punksie of spinale en epidurale narkose.
Risiko van aktiewe bloeding soos 'n bloeiende peptiese ulkus en intrakraniale bloeding.
Risiko van verhoogde bloedverlies tydens tandheelkundige en chirurgiese prosedures.

CLOPIDOGREL 75 BIOTECH moet met omsigtigheid gebruik word in pasiënte wat ander medisyne gebruik wat die risiko vir bloeding verhoog. (sien "INTERAKSIES").

In pasiënte wat nie CYP2C19 ensieme goed metaboliseer nie, vorm klopidogrel teen die aanbevole dosis minder van die aktiewe metaboliet van klopidogrel en het 'n kleiner effek op plaatjie funksie.

Aangesien klopidogrel deels gemetaboliseer word na sy aktiewe metaboliet deur die ensiem CYP2C19, word die meegaande gebruik van CLOPIDOGREL 75 BIOTECH en sterk en matige CYP2C19 inhibeerders nie aanbeveel nie (sien "INTERAKSIES").

CLOPIDOGREL 75 BIOTECH moet met omsigtigheid gebruik word in pasiënte wat 'n verhoogde risiko het van bloeding as gevolg van trauma, chirurgie, of ander patologiese toestande (sien "INTERAKSIES"). Indien 'n pasiënt elektiewe chirurgie moet ondergaan en 'n antiplaatjie uitwerking nie gewens is nie, moet CLOPIDOGREL 75 BIOTECH behandeling 7 dae voor chirurgie gestaak word.

CLOPIDOGREL 75 BIOTECH verleng bloeityd. CLOPIDOGREL 75 BIOTECH moet met omsigtigheid gebruik word in pasiënte met letsels wat neig om te bloei (soos gastroïntestinale ulkusse).
Medisyne wat sulke letsels kan induseer (soos Nie-steroïedale Anti-inflammatoriese Middels) moet met omsigtigheid gebruik word in pasiënte wat CLOPIDOGREL 75 BIOTECH neem.

Pasiënte moet ingelig word dat dit langer as normaalweg mag neem om bloeding te stop wanneer hulle CLOPIDOGREL 75 BIOTECH neem, en dat hulle enige ongewone bloeding aan hulle geneesheer moet rapporteer. Pasiënte behoort geneeshere en tandartse in te lig dat hulle klopidogrel gebruik alvorens enige chirurgie geskeduleer word en voordat enige nuwe medisyne geneem word.

Kliniese ondervinding is beperk in pasënte met swak nierfunksie en matige lewersiekte wat aan bloedingsiektes ly. CLOPIDOGREL 75 BIOTECH moet dus met omsigtigheid in hierdie groep pasiënte gebruik word.
In pasiënte met akute miokardiale infarksie, behoort CLOPIDOGREL 75 BIOTECH behandeling nie geïnisieer te word binne 'n paar dae na miokardiale infarksie nie.

Met inagneming van die gebrek aan data, kan CLOPIDOGREL 75 BIOTECH nie in onstabiele angina, PTKA (vernouing), CABG en akute iskemiese beroerte (minder as 7 dae), aanbeveel word nie.

Uitwerking op die vermoë om te bestuur en die gebruik van masjienerie
Geen inkorting van bestuursvermoë of psigometriese vaardigheid is na klopidogrel toediening waargeneem nie.

INTERAKSIES
Die gelyktydige gebruik van aspirien of Nie-steroïedale Anti-inflammatoriese Middels (NSAIMs), insluitend COX-2 inhibeerders, en CLOPIDOGREL 75 BIOTECH mag die risiko van gastroïntestinale bloeding verhoog.

Die veiligheid van gebruik van heparien en ander trombolitiese middels (insluitende warfarien) met CLOPIDOGREL 75 BIOTECH is nog nie vasgestel nie, en gelyktydige gebruik moet dus met omsigtigheid onderneem word.

CLOPIDOGREL 75 BIOTECH moet met omsigtigheid gebruik word in pasiënte wie dalk 'n risiko van verhoogde bloeding ondervind as gevolg van trauma, chirurgie of ander toestande/siektes wat dalk gesamentlike gebruik van glikoproteïen IIb/IIIa inhibeerders vereis.

CYP2C19 inhibeerders: Aangesien klopidogrel gedeeltelik na sy aktiewe metaboliet gemetaboliseer word deur CYP2C19, kan daar verwag word dat die gebruik van medisyne wat hierdie ensieme se werking inhibeer tot gevolg sal he dat die vlakke van die aktiewe matabolitet van klopidogrel verlaag word, en dus tot verlaagde inhibisie van plaatjie aggregasie aktiwiteit sal lei.
As 'n voorsorgmaatreël, word gelyktydige gebruik van sterk of matige CYP2C19 inhibeerders en CLOPIDOGREL 75 BIOTECH nie aanbeveel nie (sien WAARSKUWINGS en SPESIALE VOORSORGMAATREELS).
Medisyne produkte wat CYP2C19 inhibeer sluit in omeprasool, en esomeprasool, fluvoksamien, fluoksetien, moklobemied, vorikonasool, flukonasool, tiklopedien, siprofloksasien, simetidien, karbamasepien, okskarbasepien en klooramfenikol.

Ander gelyktydige terapie: CLOPIDOGREL 75 BIOTECH kan die aktiwiteit van een van die P450 (CYP) ensieme inhibeer (CYP2C9). Dit klan lei tot 'n verhoging in plasma vlakke van medisyne soos fenitoïen, tolbutamied, warfarien, tamoksifen, fluvastatien en baie ander (NSAIMs) wat deur CYP2C9 gemetaboliseer word.

SWANGERSKAP EN LAKTASIE
Die gebruik van CLOPIDOGREL 75 BIOTECH gedurende swangerskap en borsvoeding is nie aanbeveel nie aangesien veiligheid en effektiwiteit gedurende die gebruik daarvan nog nie vasgestel is nie (sien "KONTRA-INDIKASIES").

DOSAGE AND DIRECTIONS FOR USE
Die dosis vir volwassenes is 'n enkele daaglikse dosis van een tablet CLOPIDOGREL 75 BIOTECH, met of sonder kos.

NEWE EFFEKTE
Bloeding is die mees algemene newe effek wat aangemeld is met klopidogrel soos in CLOPIDOGREL 75 BIOTECH.

Bloed en die limfsisteem versteurings:
Minder algemeen: Trombositopenie (insluitende erge trombositopenie), leukopenie, eosinofilie, hipertensie, hematoma en bloeding van die oog (hoofsaaklik konjunktiewe en intrakraniale bloeding), neutropenie insluitend (erge neutropenie), agranulositose, pansitopenie, agranulositopenie, anemie, aplastiese anemie en trombotiese trombositopeniese purpura (TTP).

Immuunsisteem versteurings:
Hipersensitiwiteitsreaksies, soos brongospasma, angioedeem, anafilatoïede reaksies, serumsiekte.

Psigiatriese versteurings:
Minder algemeen: Hallusinasies, verwarring, angs, verstandelike depressie.

Senuweestelsel versteurings:
Minder algemeen: Hoofpyn, duiseligheid, vertigo, smaak versteurings, slapeloosheid en parestesie.

Kardiale afwykings:
Minder algemeen: Atriumfibrillasie of hartkloppings.

Vaskulêre versteurings:
Algemeen: Hematoom (sien bloed en die limfsisteem versteurings)
Minder algemeen: Edeem, ernstige bloeding, bloeding van operatiewe wond vaskulitis, hipotensie.

Respiratoriese, torakale en mediastinale versteurings:
Algemeen: Borspyn, boonste respiratoriese infeksie, epistakse.
Minder algemeen: Bloeding van die respiratoriese kanaal (hemoptise, pulmonale bloeding), brongitis, dispnee, hoes, rhinitis en interstiële pneumonitis.

Gastroïntestinale versteurings:
Algemeen: Hardlywigheid, diaree en opgeblasenheid, buik- of maagpyn, dispepsie, gastrointestinale bloeding.
Minder algemeen: Gastritis, hardlywigheid, braking, naarheid, peptiese ulkus, verlies van smaak, maagseer, duodenale ulkus, retroperitoneale bloeding (insluitend noodlottige uitkoms), pankreatitis, kolitis (insluitend ulseratiewe kolitis of limfositiese kolitis), stomatitis.

Hepato-bilière versteurings:
Minder algemeen: Akute lewerversaking, hepatitis, abnormale lewerfunksie toets.

Vel en subkutane weefsel versteurings:
Algemeen: Purpura en kneusing.
Minder algemeen: Ernstige vel reaksies insluitende blaasvorming, afskilfering of afdop van die vel, uitslag, uitslag eritemateus, bulleuse dermatitis (toksiese epidermale nekrolise, Stevens-Johnson sindroom, eriteem multiforme) jeuk, urtikarie, ekseem, lichen planus.

Muskuloskeletale, bindweefsel en been versteurings:
Minder algemeen: Gout, artralgie, rugpyn, muskuloskeletale bloeding (hemartrose), artritis, mialgie.

Renale en urinêre versteurings:
Minder algemeen: Hematurie, urienweg infeksie, glomerulonefritis, verhoogde bloed kreatinien.

Algemene- en plek van toedienings versteurings:
Algemeen: Bloeding op die plek van toediening, algemene pyn.
Minder algemeen: Sinkopee, tand versteuring, griepagtige simptome, koors, swakheid, en moegheid.

Ondersoeke:
Minder algemeen: Verlengde bloedingstyd, afname in neutrofiele telling, verminderde plaatjietelling.

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BESONDERHEDE VAN DIE BEHANDELING DAARVAN
'n Oordosis van CLOPIDOGREL 75 BIOTECH kan lei tot verlengde bloedingstyd en daaropvolgende bloeding komplikasies (sien NEWE EFFEKTE).
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE
Pienk, ronde, bikonvekse tablet.

AANBIEDING
CLOPIDOGREL 75 BIOTECH tablette word verpak in silwer poliamied/aluminium/polivinielchloried en aluminium stulpstroke. Elke karton bevat 28 tablette.

BERGINGSAANWYSINGS
Bewaar teen of onder 25 °C in 'n droë plek.
Hou die stulpstrook in die buitenste kartonhouer tot benodig word vir gebruik.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER
A45/8.4/0327

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
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Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET
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