DEPLAT Tablets

(Clopidogrel Tablet USP)

COMPOSITION:
Each film coated tablet contains:
Clopidogrel USP ... 75mg as Clopidogrel Bisulfate.
USP Specs.

DESCRIPTION:
DEPLAT (Clopidogrel Bisulfate) is an inhibitor of platelet aggregation. A variety of drugs that inhibit platelet function have been shown to decrease morbid events in people with established atherosclerotic cardiovascular disease as evidenced by stroke or transient ischemic attacks, myocardial infarction, or need for bypass or angioplasty. This indicates that platelets participate in the initiation and/or evolution of these events and that inhibiting them can reduce the event rate.

CLINICAL PHARMACOLOGY:
Mechanism of Action: Clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Biotransformation of Clopidogrel is necessary to produce inhibition of platelet aggregation, but an active metabolite responsible for the activity of the drug has not been isolated. Clopidogrel also inhibits platelet aggregation induced by agonists other than ADP by blocking the amplification of platelet activation by released ADP. Clopidogrel does not inhibit phosphodiesterase activity. Clopidogrel acts by irreversibly modifying the platelet ADP receptor. Consequently, platelets exposed to Clopidogrel are affected for the remainder of their lifespan. Dose dependent inhibition of platelet aggregation can be seen 2 hours after oral single dose of Clopidogrel.

Pharmacokinetics:
Absorption and Distribution: Clopidogrel is rapidly absorbed after oral administration of repeated doses of 75mg Clopidogrel (base), with peak plasma levels (≅ 3mg/L) of the main circulating metabolite occurring approximately 1 hour after dosing. The pharmacokinetics of the main circulating metabolite are linear in the dose range of 50 to 150mg of Clopidogrel. Absorption is at least 50% based on urinary excretion of Clopidogrel-related metabolites. Clopidogrel and the main circulating metabolite bind reversibly in-vitro to human plasma proteins (98% and 94%, respectively). The binding is nonsaturable in-vitro up to a concentration of 100mcg/ml.
Metabolism and Elimination: In-vitro and in-vivo, Clopidogrel undergoes rapid hydrolysis into its carboxylic acid derivative. In plasma and urine, the glucuronide of the carboxylic acid derivative is also observed.

INDICATIONS: DEPLAT (Clopidogrel Bisulfate) is indicated for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease.

CONTRA-INDICATIONS: The use of Clopidogrel Bisulfate is contra-indicated in the following conditions: Hypersensitivity to the drug substance or any component of the product. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

DOSAGE AND ADMINISTRATION: The recommended dose of DEPLAT (Clopidogrel Bisulfate) is one tablet daily with or without food. No dosage adjustment is necessary for elderly patients or patients with renal disease.

WARNING: Thrombotic Thrombocytopenic Purpura (TTP): TTP has been reported rarely following use of Clopidogrel Bisulfate, sometimes after a short exposure (<2 weeks). TTP is a serious condition requiring prompt treatment. It is characterized by thrombocytopenia, microangiopathic hemolytic anemia (schistocytes [fragmented RBCs] seen on peripheral smear), neurological findings, renal dysfunctions, and fever.

PRECAUTIONS: General: As with other anti-platelet agents, Clopidogrel Bisulfate should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions. If a patient is to undergo elective surgery and an antiplatelet effect is not desired, Clopidogrel Bisulfate should be discontinued 7 days prior to surgery.
GI Bleeding: Clopidogrel Bisulfate prolongs the bleeding time. In CAPRIE, Clopidogrel was associated with a rate of gastrointestinal bleeding of 2.0% vs 2.7% on aspirin. Clopidogrel Bisulfate should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers). Drugs that might induce such lesions (such as aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) should be used with caution in patients taking Clopidogrel Bisulfate.
Use in Hepatically Impaired Patients: Experience is limited in patients with severe hepatic disease, who may have bleeding diathesis. Clopidogrel Bisulfate should be used with caution in this population.
Information for Patients: Pateints should be told that it may take them longer than usual to stop bleeding when they take Clopidogrel Bisulfate, and that they should report any unusual bleeding to their physician. Patients should inform their physician and dentist that they are taking Clopidogrel Bisulfate before any surgery is scheduled and before any new drug is taken.

SIDE EFFECTS: The side effects from Clopidogrel Bisulfate are not common but in few cases any of the following symptoms may occur.

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Upset stomach, fatigue, muscle aches (flu-like symptoms), stomach pain, headache, diarrhea, constipation, rash or purple areas on skin. If you experience any of the following symptoms, consult doctor immediately. Chest pain, unusual bleeding or bruising, bloody vomit, dark urine, bloody diarrhea, tarry stools, fever, constipation, rash or purple areas on skin.

DRUG INTERACTIONS: Study of specific drug interactions yielded the following results:
Aspirin: Clopidogrel potentiated the effect of aspirin on collagen-induced platelet aggregation. The safety of chronic concomitant administration of aspirin and Clopidogrel has not been established.
Heparin: Co-administration of heparin had no effect on inhibition of platelet aggregation induced by Clopidogrel. However, concomitant use should be undertaken with caution.
Warfarin: Concomitant administration of these two agents should be undertaken with caution.
Other Concomitant Therapy: No clinically significant pharmacodynamic interactions were observed when Clopidogrel Bisulfate was co-administered with atenolol, or both atenolol and nifedipine, phenobarbital, cimetidine or estrogen, digoxin or theophylline.
Pregnancy: Clopidogrel Bisulfate should be used during pregnancy only if clearly needed.
Nursing Mothers: Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the nursing woman.
Pediatric Use: Safety and effectiveness in the pediatric population have not been established.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

AVAILABILITY: DEPLAT (Clopidogrel Bisulfate) 75mg tablets are available in a blister pack of 10's.

ڈی پلیٹ گولیاں

(کلوپی ڈوگرل)

اجزاءترکیب: ڈی پلیٹ کی ہر فلم کوٹڈ گولی میں کلوپی ڈوگرل ہائی سلفیٹ مساوی ۷۵ ملی گرام کلوپی ڈوگرل موجود ہے۔

تعارف: ڈی پلیٹ Platelets کے مکمل اجتماع اور رکاوٹ بننے سے روکتی ہے۔ جو ہارٹ اٹیک سے بچاؤ کے لئے ایک مونثر دوا ہے جو انجائنا کے مریضوں میں بھی استعمال کی جاتی ہے۔ یہ دوا Atherosclerotic Heart disease کے پہلے سے تشخیص شدہ مریضوں میں ہارٹ اٹیک اور انجائنا کے مریضوں اور ان مریضوں میں جن کو Angioplasty یا Bypass کرانا مقصود ہو استعمال کی جاتی ہے۔ جس کی وجہ سے ہارٹ اٹیک اور IHD میں مبتلا ہونے کا اندیشہ کم ہو جاتا ہے۔

علامات: ہارٹ اٹیک سے بچاؤ کے لئے ایسے مریضوں میں استعمال کی جاتی ہے جن میں Atherosclerotic diseases کے خدشات زیادہ ہوں اور دوا کے استعمال سے مریضوں میں vascular death اور myocardial infarction, stroke کے اندیشے کم ہو جاتے ہیں۔

خوراک اور طریقہ استعمال: ڈی پلیٹ (کلوپی ڈوگرل ۷۵ ملی گرام) کی ایک گولی کھانا کھانے کے بعد یا کھانا کھانے کے دوران روزانہ دی جاتی ہے۔ عمر رسیدہ اور گردے کے امراض میں مبتلا مریضوں کے لئے بھی عمومی خوراک ایک گولی روزانہ ہی ہے۔

ناپسندیدہ اثرات: بدہضمی diarrhea, constipation اور Skin rash جیسے ناپسندیدہ اثرات عام طور پر دیکھنے میں آتے ہیں۔ جبکہ کچھ مریضوں میں ذہنی تناؤ اور یرقان ہو سکتا ہے۔ اس کے علاوہ جگر کے انزائم کا نارمل حدود سے تجاوز ہونا بھی علم میں آیا ہے۔
اس کے علاوہ کچھ مریضوں میں taste loss اور joint pain کی شکایات علم میں آئی ہیں۔

مانع علامات: کلوپی ڈوگرل ہائی سلفیٹ سے پیشگی حساسیت، جن مریضوں کا Bleeding time نارمل سے زیادہ ہو ایسے مریضوں کو دوا کے استعمال سے گریز کرنا چاہئے اس کے علاوہ معدے اور آنتوں کے السر میں مبتلا مریض اور Intracranial haemorrhage کے مریضوں کو دوا کے استعمال سے گریز کرنا چاہئے۔

دوسری دواؤں کے ساتھ ردعمل: ڈی پلیٹ گولیاں (کلوپی ڈوگرل) کا دیگر ادویات مثلاً Aspirin, Heparin, NSAIDs اور Warfarin کے ساتھ استعمال احتیاط سے کریں۔

اطلاع برائے مریض: وہ مریض جو ڈی پلیٹ گولیاں (کلوپی ڈوگرل) استعمال کر رہے ہوں اور ان کو Surgery یا Dental procedure کرانا مقصود ہو تو ڈاکٹر کو اپنے ڈی پلیٹ کے استعمال سے آگاہ کریں کیونکہ بعض دفعہ کلوپی ڈوگرل استعمال کرنے والے مریضوں کے زخم سے خون کے اخراج کو روکنا مشکل ہو سکتا ہے۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

طریقہ فراہمی: ڈی پلیٹ (کلوپی ڈوگرل) ۷۵ ملی گرام گولیاں 10's کے بلسٹر پیک میں دستیاب ہیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.
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