

ڈوگرل®

کلو پیڈوگرل یو ایس پی ۷۵ ملی گرام

خوراک:

ڈوگرل کی تجویز کردہ خوراک ۷۵ ملی گرام دن میں صرف ایک بار ہے جو کھانے کے ساتھ یا کھانے کے بغیر لی جاسکتی ہے۔ عمر رسیدہ یا گردے کے مریض کے لئے تجویز کردہ خوراک میں ردوبدل ضروری نہیں ہے۔

ہدایات:

- * دوا کو ٹھنڈی اور خشک جگہ پر رکھیں۔
- * دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔
- * دوا صرف ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔
- * تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

پیشکش:

ڈوگرل فلم کوئڈ گولیاں (۶x۲) ایلو۔ ایلو پیک میں دستیاب ہیں۔



Manufactured by:

Schazoo Zaka (Pvt) Ltd.

Kalalwala, 20-Km Lahore-Jaranwala Road,
Distt: Sheikhpura, Pakistan.

Dogrel®

Clopidogrel U.S.P. 75 mg

COMPOSITION: Each film coated tablet contains Clopidogrel (as bisulphate) U.S.P. 75 mg.

CLINICAL PHARMACOLOGY:

Pharmacodynamics:

Dogrel (clopidogrel) selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor & 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 life span.

Pharmacokinetics:

Clopidogrel is rapidly absorbed after oral administration of repeated doses of 75mg clopidogrel (base), with peak plasma levels (=3 mg/L) of the main circulating metabolite occurring approximately 1 hour after dosing. Clopidogrel is extensively metabolized by the liver. The main circulating metabolite is the carboxylic acid derivative, and it has no effect on platelet aggregation. It represents about 85% of the circulating drug-related compounds in plasma. Clopidogrel undergoes rapid hydrolysis into its carboxylic acid derivative. In plasma and urine, the glucuronide of the carboxylic acid derivative is also observed.

Following an oral dose of ¹⁴C-labeled clopidogrel in humans, approximately 50% was excreted in the urine & approximately 46% in the feces in the 5 days after dosing. The elimination half-life of the main circulating metabolite is 8 hours after single & repeated administration. Covalent binding to platelets accounted for 2% of radiolabel with a half-life of 11 days.

INDICATIONS:

Dogrel 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.

DOSAGE & ADMINISTRATION:

The recommended dose of **Dogrel** is one tablet once daily with or without food. No dosage adjustment is necessary for elderly patients or patients with renal disease.

CONTRA-INDICATIONS:

Dogrel 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 intra-cranial hemorrhage.

PRECAUTIONS & WARNINGS:

General:

As with other anti-platelet agents, Clopidogrel should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions.

GI Bleeding:

Clopidogrel should be used with caution in patients who have lesions with a propensity to bleed (such as ulcers).

Pregnancy:

Clopidogrel should be used during pregnancy only if clearly needed.

Nursing mothers:

It is not known whether this drug is excreted in human milk. 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.

DRUG INTERACTIONS:

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. The safety of this combination has not been established, however, concomitant use should be undertaken with caution.

NSAIDs:

In healthy volunteers receiving naproxen, concomitant administration of Clopidogrel was associated with increased occult gastrointestinal blood loss. NSAIDs and Clopidogrel should be co-administered with caution.

Warfarin: The safety of the co-administration of Clopidogrel with warfarin has not been established. Consequently, concomitant administration of these two agents should be undertaken with caution.

SIDE EFFECTS:

ANS disorders: Syncope, Palpitation.

CVS disorders: Cardiac failure, Generalized edema.

Central And Peripheral nervous system disorders: Legs Cramps, Hypoaesthesia, Neuralgia, Paresthesia, Vertigo.

GIT disorders: Constipation, Vomiting, Perforated gastric ulcer, Gastritis hemorrhagic.

Liver and biliary system disorders: Hepatic enzymes increased, Bilirubinemia, Infectious hepatitis, Fatty liver.

Metabolic and nutritional disorders: Gout, Hyperuricemia, Non-protein nitrogen (NPN) increased.

Musculo-skeletal system disorders: Arthritis, Arthrosis.

Platelet, Bleeding & Clotting disorders: GI hemorrhage, Hematoma, Platelets decreased, Hemarthrosis, Hematuria, Hemoptysis, Intracranial hemorrhage, Retroperitoneal hemorrhage, Hemorrhage of operative wound, Ocular hemorrhage, Pulmonary hemorrhage, Purpura allergic, Thrombocytopenia.

RBC disorders: Anemia, Aplastic anemia, Hypochromic anemia.

Psychiatric disorders: Anxiety, Insomnia.

Respiratory system disorders: Pneumonia, Sinusitis, Hemothorax.

Skin and appendage disorders: Eczema, Skin ulceration, Bullous eruption, Rash, Erythematous, Urticaria.

Urinary system disorders: Cystitis.

Vision disorders: Cataract, Conjunctivitis

Body as whole: Allergic reaction, Necrosis ischemic.

Reproductive disorders: Female: Menorrhagia

OVERDOSAGE:

No adverse events were reported after single oral administration of 600 mg (equivalent to 8 standard 75 mg tablets) of Clopidogrel in healthy volunteers.

Treatment:

Based on biological plausibility, platelet transfusion may be appropriate to reverse the pharmacological effects of Clopidogrel if quick reversal is required

STORAGE CONDITIONS:

- * Store in a cool and dry place.
- * Protect from heat, light and moisture
- * Keep all medicines out of the reach of children.

PACKING:

Dogrel tablets are available in (2x6) Alu-Alu blister pack.