Noclog Plus®

Clopidogrel bisulfate USP and
Aspirin USP film coated tablet

DESCRIPTION

Noclog Plus® is a fixed dose combination containing clopidogrel and aspirin. Clopidogrel is an inhibitor of platelet aggregation. Clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP mediated activation of the glycoprotein (GP) IIb/IIIa complex, thereby inhibiting platelet aggregation. Aspirin is also an antiplatelet agent. It acts by causing irreversible inhibition of the cyclo-oxygenase enzyme, which leads to decreased formation of the thromboxane A_2. Since platelet does not synthesize new enzyme, the action of aspirin on platelet cyclo-oxygenase is permanent, lasting for the life of the platelet (7-10 days).

INDICATIONS

Prevention of atherosclerotic events in patients with history of symptomatic atherosclerotic diseases (e.g. ischemic stroke, myocardial infarction or acute coronary syndrome).

DOSAGE AND ADMINISTRATION

The recommended dose is one tablet once daily.

PHARMACOKINETICS

Absorption and Distribution: The absorption of clopidogrel is >50% and is rapid after oral administration. Bioavailability is unaffected by food. Both the parent compound and the main metabolite bind reversibly in vitro to plasma protein (98% and 94% respectively). After oral administration, aspirin is rapidly absorbed from the stomach and proximal small intestine. The gastric mucosa is permeable to the nonionised form of aspirin, which passes through the stomach wall by a passive diffusion process. Aspirin is distributed throughout most body fluids and tissues. Concentrations in the brain are usually low and are minimal in feces, bile and sweat.

Metabolism and Elimination: Clopidogrel is extensively metabolised by the liver. It undergoes rapid hydrolysis into its carboxylic acid derivative; glucoronidation also occurs. The elimination half life of the main circulating metabolite is 8 hours with

50% excretion in the urine and 46% in the feces 5 days after dosing. Aspirin is rapidly hydrolysed primarily in the liver to salicylic acid, which is conjugated with glycine and glucoronic acid and excreted largely in the urine. The plasma half life for aspirin is approximately 15 minutes.

CONTRAINDICATIONS

Combination of clopidogrel and aspirin is contraindicated in patients with known hypersensitivity to any of the components or NSAIDs, active pathological bleeding such as peptic ulcer or intracranial hemorrhage or bleeding disorders like hemophilia and in patients with recent history of gastrointestinal bleeding.

SIDE-EFFECTS

The combination is generally well tolerated. Side effects that have been reported include abdominal pain, nausea, vomiting, neuralgia, paresthesia, rash, pruritis.

USE IN PREGNANCY AND LACTATION

The combination drug should be avoided during pregnancy. It is not recommended for use during breast feeding because of the possible risk of developing Reye's Syndrome.

USE IN PAEDIATRIC PATIENTS

Safety and efficacy in the paediatric population have not been established.

DRUG INTERACTIONS

Combination of clopidogrel and aspirin may enhance the effect of anticoagulants.

PHARMACEUTICAL PRECAUTIONS

Store in a cool (below 30 °C) and dry place, away from light. Keep out of reach of children.

PACKAGING

Noclog Plus® Tablet: Box containing 4 strips of 10 tablets each. Each film coated tablet contains clopidogrel bisulfate USP equivalent to clopidogrel 75 mg and aspirin USP 75 mg.

SK+F
Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH
® REGD. TRADEMARK
PM04630 V01