Anclog® Plus

Clopido grel INN and + Aspirin BP

PRESENTATION

Anclog[®] Plus Tablet: Each film-coated tablet contains Clopidogrel 75 mg as Clopidogrel bisulfate INN + Aspirin BP 75 mg

PHARMACOLOGY

Anclog[®] 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 GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Aspirin is also an antiplatelet agent. It acts by causing irreversible inhibition of the cyclo-oxygenase enzyme.

MECHANISM OF ACTION

Clopidogrel is a thienopyridine derivative that interferes with the platelet activation cascade. It blocks the adenosine diphosphate (ADP)

receptor selectively and irreversibly & thus inhibiting the activation of the GPIIb/IIIA complex, the major receptor fibrinogen present in the platelet surface. Clopidogrel may antagonize the ADP induced

inhibition of the atenylate cyclase possibly resulting in an elevated platelet cyclic adenosine monophosphate level after stimulation by an appropriate agonist. 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 A2. 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)

PHARMACOKINETICS

Absorption/Distribution:

The absorption of clop idogrel 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/Elimination:

Clopidogrel is extensively metabolised by the liver. It undergoes rapid hydrolys is into its carboxylic acid derivative; glucoronidation also occurs. The elimination half life of the main circulating metabolite is 8 hrs with 50% excreted 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.

INDICATIONS AND USES

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

DOSAGE & ADMINISTRATION

The recommended dose is one tablet once daily.

CONTRAINDICATIONS

Hypersensitivity to any of the components or NS AIDs. Active pathological bleeding such as peptic ulcer or intracranial hemorrhage or bleeding disorders like hemophilia. Recent history of gastro intestinal bleeding.

SIDE EFFECTS

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

DRUG INTERACTION

This combination may enhance the effect of anticoagulants.

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 Reve's syndrome.

USE IN PEDIATRIC PATIENTS

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

STORAGE CONDITION

Store in a cool and dry place. Protect from light and moisture.

PACKAGE QUANTITIES

Anclog® Plus tablet - Each box contains 30 tablets in blister pack.