

# CLOPIDOGREL

## ACUVAN

75 mg Film-Coated Tablet

*Antithrombotic*



### FORMULATION:

Each film-coated tablet contains:

Clopidogrel (as bisulfate) ..... 75 mg

### PHARMACODYNAMICS/PHARMACOKINETICS:

Clopidogrel is a thienopyridine antiplatelet drug used in patients who are at risk for thromboembolic disorders. Clopidogrel is a ticlodipine analogue which reduces platelet aggregation by inhibiting the adenosine diphosphate pathway. Clopidogrel works by irreversibly blocking the ADP-receptor on platelets thereby inhibiting aggregation. It is given prophylactically as an alternative to aspirin in patients with atherosclerosis who are at risk for disease and stroke. Clopidogrel is given in combination with aspirin to reduce myocardial infarction and unstable angina. It is also used in preventing thrombosis in patients undergoing coronary stenting.

Following oral administration, clopidogrel is rapidly but incompletely absorbed; absorption appears to be about 50%. It is extensively metabolized in the liver mediated by the cytochrome P450 isoenzymes including CYP3A4, CYP2BC, CYP1A2, CYP1A1, and CYP2C19 mainly to the inactive carboxylic acid derivative. The active metabolites appear to be a thiol derivative which has been identified in vitro but appears to be unstable to be isolated from plasma. Clopidogrel and its carboxylic acid derivatives are highly protein bound. Clopidogrel and its metabolites are excreted about equally in urine and in feces.

### INDICATIONS:

Clopidogrel is an antiplatelet drug used in thromboembolic disorders. It is given as prophylaxis for patients with atherosclerosis, who are at risk for thromboembolic disorders such as myocardial infarction, peripheral arterial disease, and stroke prevention. Clopidogrel may be given with aspirin in acute coronary syndromes including unstable angina and myocardial infarction. It is also used in preventing thrombosis in patients undergoing coronary stenting and in patients allergic to aspirin.

### DOSAGE AND ADMINISTRATION:

The usual dose is 75 mg once daily for prophylaxis of thromboembolic events.

For acute ST- elevation myocardial infarction, the dose is 75mg once daily, and for patients under 75years old, 300mg as loading dose may be given and treatment should be continued for at least 4 weeks.

For patients with unstable angina and non-Q-wave myocardial infarction, a single loading dose of 300mg is given followed by 75mg once daily.

Or as prescribed by the physician.

### CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:

Clopidogrel is contraindicated in patients with history of hypersensitivity to the drug and its components.

Clopidogrel should not be given to patients with pathologic bleeding. Hematopoietic disorders such as neutropenia or thrombocytopenia and other hemorrhagic disorders associated with prolonged bleeding time or condition with increased risk of bleeding such as gastrointestinal ulcers acute cerebral hemorrhage or severe liver dysfunction.

Routine blood cell counts should be performed before starting treatment and every 2 weeks during the first 3 months of therapy or when clinical signs suggest blood dyscrasias. If clopidogrel is discontinued during this period, a full blood count should be performed within 2 weeks of stopping treatment. Consideration should be given in stopping the therapy 5 to 7 days before elective surgery. Clopidogrel should be used with caution in patients receiving ASA, non-steroidal anti-inflammatory drugs, and heparin.

Clopidogrel should not be concomitantly administered with warfarin since it may increase the intensity of bleeding.

### PREGNANCY AND LACTATION:

There are no adequate and well controlled clinical studies in pregnant and lactating women. Clopidogrel should not be used during pregnancy. It is not known whether clopidogrel is excreted in human milk.

### ADVERSE DRUG REACTIONS:

Hypersensitivity reactions including angioedema have been reported. There have also been reports of a hypersensitivity syndrome with fever, rash, and other varying symptoms. Routine blood counts should be done promptly whenever clinical signs suggest blood dyscrasias. Other rare adverse effects reported include serum sickness, interstitial pneumonitis, erythema multiforme, Stevens-Johnson syndrome, lichen planus, myalgia, and loss of taste.

Other adverse effects include headache, dizziness, paresthesia, dyspepsia, gastrointestinal bleeding, and abdominal pain.

Blood disorders may be encountered including purpura, bruising, hematoma, hematuria, conjunctival bleeding, epistaxis, intracranial bleeding, increased bleeding time, reduced platelets, leucopenia, decreased neutrophils, and eosinophilia.

### DRUG INTERACTIONS:

Clopidogrel should be used with caution in patients receiving other drugs that increase the risk of bleeding, such as anticoagulants, antiplatelets, and NSAIDs. It may inhibit the metabolism of other drugs that are metabolized in the liver. The antiplatelet effect of clopidogrel may be reduced when it is taken with drugs that inhibit the activity of cytochrome P450 isoenzymes. Cimetidine reduces clearance of clopidogrel. The effect of clopidogrel on bleeding time maybe antagonized by corticosteroids. Clopidogrel may interact with aspirin, ketoconazole, bupropion, ciclosporin, statins, and proton pump inhibitors.

### OVERDOSAGE AND TREATMENT:

Bleeding complication may be observed in clopidogrel overdosage which is characterized by prolonged bleeding time. Appropriate measures should be done if there are signs of bleeding. There is no antidote for clopidogrel overdose, however a prompt correction of prolonged bleeding time is necessary and platelet transfusion may be warranted.

### AVAILABILITY:

Alu-alu blister pack of 10's (Box of 30's)

### CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

DR-XY43822

**STORE AT TEMPERATURES NOT EXCEEDING 30°C**

**PROTECT FROM LIGHT**

For suspected adverse drug reaction, report to the FDA:  
[www.fda.gov.ph](http://www.fda.gov.ph)

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