

# Dorel

## Clopidogrel Tablet

### Presentation

**Dorel Tablet:** Each film coated tablet contains Clopidogrel Bisulphate USP equivalent to Clopidogrel 75 mg.

### Indications

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

### Dosage and administration

#### *Adults and elderly*

The recommended dose of Clopidogrel is 75 mg once daily. It can be taken with or without food. No dosage adjustment is necessary for elderly patients or patients with renal disease.

#### *Children and adolescents*

Safety and efficacy below the age of 18 years have not been established.

### Contraindications

- Hypersensitivity to the drug substance or any component of the product.
- Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

### Side effects

The tolerability of Clopidogrel is similar to that of aspirin. Diarrhea, rash, or itching occur in approximately 1 in 20 persons taking Clopidogrel. Abdominal pain also occur in about 1 in 20 persons, but it is less frequent than with aspirin.

### Precautions

As with other antiplatelet agents, Clopidogrel should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery or other pathological conditions. Clopidogrel should be discontinued 7 days prior to surgery. Clopidogrel should be used with caution in patients who have ulcer or in hepatically impaired patients who may have bleeding diatheses.

### Use in pregnancy and lactation

#### *Pregnancy*

There are no adequate studies of Clopidogrel in pregnant women. Therefore, it can be used in pregnancy if the physician determines that it is needed.

#### *Nursing mothers*

It is not known whether it appears in human breast milk. Because of a potential for side-effects in the nursing infant, the physician must weigh the potential benefits and possible risks before prescribing this drug in nursing mothers.

### Drug interactions

The combination of Clopidogrel with NSAIDs may increase the risk of stomach and intestinal bleeding. At high concentration in the blood, Clopidogrel inhibits the activity of the enzyme which metabolizes Warfarin and increases the risk of bleeding due to over-thinning of the blood.

### Overdose

No adverse events were reported.

### Storage Conditions

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

### Commercial pack

**Dorel Tablet:** Each box contains 3 blister packs of 10 tablets.

Manufactured by:

 **GENERAL**  
Pharmaceuticals Ltd.  
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