

Torpedo-75

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Clopidogrel Bisulphate Tablets

COMPOSITION

TORPIDO-75

Each film-coated tablet contains:

Clopidogrel (as bisulfate) 75 mg

INDICATIONS

• Acute Coronary Syndrome

- For patients with non-ST-segment elevation ACS [unstable angina (UA)/non-ST-elevation myocardial infarction (NSTEMI)], including patients who are to be managed medically and those who are to be managed with coronary revascularization, clopidogrel has been shown to decrease the rate of a combined endpoint of cardiovascular death, myocardial infarction (MI), or stroke as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia.
- For patients with ST-elevation myocardial infarction (STEMI), clopidogrel has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction, or stroke. The benefit for patients who undergo primary percutaneous coronary intervention is unknown.

The optimal duration of clopidogrel therapy in ACS is unknown.

• Recent Myocardial Infarction, Recent Stroke or Established Peripheral Arterial Disease [®]

For patients with a history of recent myocardial infarction (MI), recent stroke, or established peripheral arterial disease, clopidogrel has been shown to reduce the rate of a combined endpoint of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular deaths.

DOSAGE AND ADMINISTRATION

• Acute Coronary Syndrome

Clopidogrel can be administered with or without food.

- For patients with non-ST-elevation ACS (UA/NSTEMI), initiate clopidogrel with a single 300 mg oral loading dose and then continue at 75 mg once daily. Initiate aspirin (75–325 mg once daily) and continue in combination with clopidogrel.
- For patients with STEMI, the recommended dose of clopidogrel is 75 mg once daily orally, administered in combination with aspirin (75–325 mg once daily), with or without thrombolytics. Clopidogrel may be initiated with or without a loading dose

• Recent MI, recent stroke or established PAD

The recommended dose is 75 mg once daily orally, with or without food.

CYP2C19 Poor Metabolizers

CYP2C19 poor metabolizer status is associated with diminished antiplatelet response to clopidogrel. Although a higher dose regimen (600 mg loading dose followed by 150 mg once daily) in poor metabolizers increases antiplatelet response, an appropriate dose regimen for this patient population has not been established in clinical outcome trials.

CONTRAINDICATIONS

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

PACKAGING INFORMATION

TORPIDO-75 Alu-Alu Blister of 10 Tablets