Skin and subcutaneous tissue disorders: patients with a history of hypersensitivity or hematologic reaction to other thienopyridines should be treated with caution.

DOSAGE AND ADMINISTRATION

- Acute coronary syndromes (ACS)
  - For ACS patients with non-ST-elevation ACS (UA/NSTEMI), initiate clopidogrel with a single 300 mg oral loading dose and then administer 75 mg per day for 48 hours.
  - For ACS patients in high-risk trials, initiate clopidogrel with a single 300 mg oral loading dose and then administer 75 mg per day for 12 months.

- In patients with recent MI or recent ischemic stroke, administer clopidogrel as described above after a single 300 mg oral loading dose and then administer 75 mg per day.

- In patients with acute coronary syndrome (ACS) or with recent ST-elevation myocardial infarction (STEMI), clopidogrel should be administered as described above within 24 hours of percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG).

- For patients undergoing CABG, administer clopidogrel in combination with oral aspirin. If clopidogrel is administered after CABG, do not administer for at least 5 days prior to elective surgery or other surgery where bleeding is likely to be increased.

CONTRAINDICATIONS

- Active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

5.1 Diminished Antiplatelet Activity Due to Impaired CYP2C19 Function

Clopidogrel is contraindicated in patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage.

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All treated patients received aspirin. Unexpected bleeding or bleeding that lasts a long time.

Patients were randomized to receive clopidogrel (75 mg once daily) or placebo, in combination with aspirin (162 mg per day), for the study, COMMIT. COMMIT included 45,852 patients presenting within 24 hours of the onset of the symptoms of myocardial infarction. In patients with STEMI, the safety and efficacy of clopidogrel were evaluated in the randomized, placebo-controlled, double-blind trial, COMMIT. COMMIT did not affect the number of patients treated with CABG or PCI (with or without stenting), (2253 patients [36.0%] in the clopidogrel group, 454 patients [7.2%] in the placebo group, relative risk reduction of 18%). The use of clopidogrel in CURE was associated with a decrease in the use of thrombolytic therapy (71 patients [1.1%] in the clopidogrel group, 106 patients [1.7%] in the placebo group, relative risk reduction of 60%).

The use of clopidogrel in CURE was associated with a decrease in the use of thrombolytic therapy. The use of clopidogrel in CURE was associated with a decrease in the use of thrombolytic therapy.

Figure 5: Cumulative Event Rates for the Combined Endpoint Re-Infarction, Stroke or Death in the COMMIT Study.

**Figure 5: Combined Endpoint Re-Infarction, Stroke or Death in the COMMIT Study**

**Figure 6: Effects of Adding Clopidogrel to Aspirin on the Combined Primary Endpoint across Baseline and Concomitant Medication Subgroups for the COMMIT Study**

**Figure 6: Effects of Adding Clopidogrel to Aspirin on the Combined Primary Endpoint across Baseline and Concomitant Medication Subgroups for the COMMIT Study**

Aspirin

**Figure 6: Effects of Adding Clopidogrel to Aspirin on the Combined Primary Endpoint across Baseline and Concomitant Medication Subgroups for the COMMIT Study**

Clopidogrel

Clopidogrel

Placebo

Placebo

<table>
<thead>
<tr>
<th>Event Subgroups for the COMMIT Study</th>
<th>Clopidogrel</th>
<th>Placebo</th>
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