HCP-MEPPO
Publishers of MEPPO and MODERN MEDICINE
08-15

# CLOPACIN®
## *ACINO SWITZERLAND*

**Composition:**
Clopacin® active ingredient is clopidogrel besilate. Each film-coated tablet contains 75 mg of clopidogrel. Clopacin® contains hydrogenated castor oil, which may cause stomach upset and diarrhoea.

**Indications and dosage:**
Clopacin® is an anti-platelet agent, acting as a platelet adenosine diphosphate (ADP) receptor antagonist, inhibiting platelet aggregation for the lifetime of the platelet (7-10 days).

Clopacin® is indicated for the prevention of atherothrombotic events in:

*(1) adult patients with history of recent myocardial infarction* (from a few days until less than 35 days), recent ischemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease;

*(2) adult patients with acute coronary syndrome (ACS), either (i) NSTEMI (Non-ST Elevation Myocardial Infarction:* unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA); or (ii) STEMI (ST Elevation Myocardial Infarction), in combination with ASA in medically treated patients eligible for thrombolytic therapy. Clopacin® should be given as a single daily dose of 75 mg with or without food.

*Initiation of treatment for NSTEMI:* single loading dose of 300 mg of Clopacin®, then Clopacin® 75 mg once a day in combination with ASA (ASA dose recommended to be not higher than 100 mg).

*Initiation of treatment for STEMI:* single loading dose of 300 mg of Clopacin®, then Clopacin® 75 mg once a day with ASA and with or without thrombolytics.

For patients over 75 year-old, Clopacin® treatment should be initiated without loading dose.

**Contraindications:**
Hypersensitivity to the active substance or to any of the excipients, severe liver impairment, active pathological bleeding such as peptic ulcer or intracranial haemorrhage.

**Precautions:**
*(i) risk of bleeding & haematological adverse reactions:* caution is to be exercised in patients at risk of increased bleeding (from trauma, surgery, pathological conditions) and in patients receiving treatment with ASA, heparin, glycoprotein IIb/IIIa inhibitors or NSAIDs (including Cox-2 inhibitors). Concomitant administration of Clopacin® with oral anti-coagulants is not recommended. Clopacin® treatment should be discontinued 7 days prior to surgery (including dental surgery);

*(ii) Thrombotic Thrombocytopenic Purpura (TTP):* TTP has been reported very rarely following the use of Clopacin®, sometimes after a short exposure. It is a potentially fatal condition requiring prompt treatment that includes plasmapheresis;

*(iii) recent ischaemic stroke:* Clopacin® cannot be recommended during the first 7 days after acute ischaemic stroke;

*(iv) CYP2C19 metabolism:* Clopidogrel is metabolised to its active metabolite partly by CYP2C19. Patients with genetically reduced CYP2C19 metabolism will have a lower systemic exposure to the active metabolite of clopidogrel and a diminished antiplatelet response. Concomitant use of Clopacin® with CYP2C19 inhibitors should be discouraged;

*(v) renal impairment:* caution should be exercised in patients with renal impairment;

*(vi) hepatic impairment:* caution should be exercised in patients with moderate hepatic disease who may have bleeding diatheses.

**Pregnancy / lactation:**
It is preferable not to use Clopacin® during pregnancy and to discontinue Clopacin® treatment during breast-feeding.

**Undesirable effects:**
Bleeding is the most common adverse event and is mostly reported during the first month of treatment.

Bleeding may occur as gastrointestinal haemorrhage, bruising, haematoma, epistaxis, haematuria, eye bleeding, bleeding in the lungs or the joints, or intracranial bleeding. Other reported side effects include diarrhoea, abdominal pain, dyspepsia, headache, dizziness, paraesthesia, thrombocytopenia.

**Interactions:**

Caution should be exercised in patients receiving concomitant treatment of clopidogrel with the following medicines:

(i) Oral anticoagulants: intensity of bleedings may be increased;
(ii) Glycoprotein IIb/IIIa inhibitors;
(iii) ASA;
(iv) Heparin;
(v) Thrombolytics;
(vi) NSAIDs;
(vii) CYP2C19 inhibitors: Clopidogrel is metabolized to its active metabolite in part by CYP2C19.

Concomitant use of drugs that inhibit the activity of this enzyme results in reduced plasma concentrations of the active metabolite of clopidogrel and a reduction in platelet inhibition.

**Presentation:**

14, 28, 30, 50, 84, 90 and 100 film-coated tablets.

Since indications, dosage forms and strengths may vary from country to country, please consult your local prescribing information. Full prescribing information, details and literature references are available on request. Latest update of information: March 2011.

**Clopacin® - Acino's clopidogrel besilate - is approved for use by the European Medicines Agency (EMA) and by the Swiss Agency for Therapeutic Products (Swissmedic), under the names of Clopidogrel Acino and Clopidogrel-Acino 75, respectively.**