Prasurel®

765

Prasugrel Hydrochloride INN tablet

Presentation

Prasurel® 5: Each tablet contains Prasugrel Hydrochloride INN equivalent to prasugrel 5 mg.
Prasurel® 10: Each tablet contains Prasugrel Hydrochloride INN equivalent to prasugrel 10 mg.

Description

Prasurel is an inhibitor of platelet activation and aggregation through the irreversible binding of its active metabolite to the P2Y12 class of ADP receptors on platelets.

Indications and uses

Prasurel is indicated to reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI) as follows:

- Patients with unstable angina (UA) or non-ST-elevation myocardial infarction (NSTEMI).
- Patients with ST-elevation myocardial infarction (STEMI) when managed with primary or delayed PCI.

Dosage & administration

Treatment should be initiated with a single 60 mg oral loading dose.

- Continue at 10 mg once daily with or without food. Consider 5 mg once daily for patients < 60 kg.
- Patients should also take aspirin (75 mg to 325 mg) daily.

Side-effects

- Bleeding
- Thrombotic thrombocytopenic purpura
- Other side effects (Headache, back pain, dyspnea, nausea,hypertension, bradycardia, rash etc)

Contraindications

- Active pathological bleeding such as peptic ulcer or intracranial hamorrhage
- Patient with a history of prior transient ischemic attack or stroke

Precaution

- CABG-related bleeding: Risk increases in patients receiving Prasurel who undergo CABG.
- Discontinuation of Prasugrel: Premature discontinuation increases risk of stent thrombosis, MI, and death

Pregnancy

Pregnancy Category B - There are no adequate and well-controlled studies of Prasugrel use in pregnant women. Reproductive and developmental toxicology studies in rats and rabbits at doses of up to 30 times the recommended therapeutic exposures in humans revealed no evidence of fetal harm; however, animal studies are not always predictive of a human response.

Nursing Mothers

It is not known whether Prasugrel is excreted in human milk. Because many drugs are excreted in human milk, prasugrel should be used during nursing only if the potential benefit to the mother justifies the potential risk to the nursing infant.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established

Geriatric Use

Patients' > 75 years of age who received Prasugrel had an increased risk of fatal bleeding events (1.0%) compared to patients who received clopidogrel (0.1%).

Renal Impairment

No dosage adjustment is necessary for patients with renal impairment. There is limited experience in patients with end-stage renal disease

Hepatic Impairment

No dosage adjustment is necessary in patients with mild to moderate hepatic impairment

Drug interaction

- Coadministration of Prasugrel and warfarin increases the risk of bleeding.
- Coadministration of Prasugrel and NSAIDs (used chronically) may increase the risk of bleeding.
- Prasurel can be administered with drugs that are inducers or inhibitors of cytochrome P450 enzymes. Prasurel can be administered with aspirin (75 mg to 325 mg per day), heparin, GPIIb/IIIa inhibitors, statins, digoxin, and drugs that elevate gastric pH, including proton pump inhibitors and H2 blockers.

Overdosage

In rats, lethality was observed after administration of 2000 mg/kg. Platelet transfusion may restore clotting ability. The prasugrel active metabolite is not likely to be removed by dialysis.

Storage

Do not store above 30° C. Keep out of the reach of children.

Commercial Pack

Prasurel® 5: Each box contains 3 blister strips of 10 tablets.
Prasurel® 10: Each box contains 2 blister strips of 10 tablets.

Manufactured by
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Savar, Dhaka, Bangladesh
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