

Ticarel™

Ticagrelor 60 & 90 mg

Presentation

Ticarel™ 60: Each tablet contains Ticagrelor INN 60 mg.

Ticarel™ 90: Each tablet contains Ticagrelor INN 90 mg.

Description

Ticagrelor, a cyclopentyltriazolopyrimidine which is a reversible platelet aggregation inhibitor. Ticagrelor reversibly binds with the platelet P2Y₁₂ adenosine diphosphate (ADP) receptor and thereby inhibits signal transduction and platelet aggregation.

Indications and usage

Ticarel is a P2Y₁₂ platelet inhibitor indicated

• To reduce the risk of cardiovascular (CV) death, myocardial infarction (MI), and stroke in patients with acute coronary syndrome (ACS) or a history of MI. For at least the first 12 months following ACS, it is superior to clopidogrel.

Ticarel also reduces the risk of stent thrombosis in patients who have been stented for treatment of ACS.

• To reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Ticarel was established in a population with type 2 diabetes mellitus (T2DM).

Dosage and administration

ACS or History of MI

In the management of ACS, initiate treatment with 180 mg oral loading dose. Then administer 90 mg twice daily during the first year. After one year, administer 60 mg twice daily.

Patients with CAD and No Prior Stroke or MI

Administer 60 mg twice daily. Use Ticarel with a daily maintenance dose of aspirin of 75-100 mg.

Side-effects

- Bleeding
- Dyspnea

Contraindications

- History of intracranial hemorrhage.
- Active pathological bleeding.
- Hypersensitivity to ticagrelor or any component of the product.

Precautions

General Risk of Bleeding

Drugs that inhibit platelet function including Ticagrelor increase the risk of bleeding.

Concomitant Aspirin Maintenance Dose

Use of Ticagrelor with maintenance doses of aspirin above 100 mg decreased the effectiveness of Ticagrelor. Therefore, after the initial loading dose of aspirin (usually 325 mg), use Ticagrelor with a maintenance dose of aspirin of 75-100 mg.

Severe Hepatic Impairment

Likely increase in exposure to Ticagrelor. Avoid use of Ticagrelor in patients with severe hepatic impairment.

Discontinuation of Ticagrelor

Discontinuation of Ticagrelor will increase the risk of myocardial infarction, stent thrombosis, and death.

Pregnancy and lactation

Pregnancy Category C. There are no adequate and well-controlled studies of Ticagrelor used in pregnant women. It is not known whether Ticagrelor or its active metabolites are excreted in human milk.

Pediatric Use

The safety and effectiveness of Ticagrelor in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed in patients of ≥75 years of age and younger patients.

Hepatic Impairment

Ticagrelor has not been studied in the patients with moderate or severe hepatic impairment. Ticagrelor is metabolized by the liver and impaired hepatic function can increase risks for bleeding and other adverse events.

Renal Impairment

No dosage adjustment is needed in patients with renal impairment. Patients receiving dialysis have not been studied.

Overdosage

Other effects of overdose may include gastrointestinal effects (e.g. nausea, diarrhoea) or ventricular pauses. Proper management should be taken through ECG monitoring in severe bleeding.

Drug interactions

Avoid use of strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin). Use of Ticagrelor with aspirin maintenance doses above 100 mg reduced the effectiveness of Ticagrelor. Ticagrelor will result in higher serum concentrations of simvastatin or lovastatin because these drugs are metabolized by CYP3A.

Storage


Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial pack

Ticarel™ 60: Each box contains 2 blister strips of 10 tablets.

Ticarel™ 90: Each box contains 2 blister strips of 10 tablets.

Manufactured by

 **Incepta Pharmaceuticals Ltd**

Savar, Dhaka, Bangladesh

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