Tiga

Tablet

DRUG INTERNATIONAL LTD.

Composition : Each film coated tablet contains Ticagrelor 90mg as Ticagrelor Hydrochloride INN.

Pharmacology : Ticagrelor, a cyclopentyl triazolopyrimidine and its major metabolite AR-C124910XX reversibly interact with the platelet $P2Y_{12}$ADP-receptor to prevent signal transduction and platelet activation. Ticagrelor and its active metabolite are approximately equipotent. The mean $t_{1/2}$ is approximately 7 hours for ticagrelor and 9 hours for the active metabolite. Bioavailability is about 36% and eliminated 58% in feces, 26% in urine.

Indications : Ticagrelor is indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction). It has been shown to reduce the rate of cardiovascular death, myocardial infarction or stroke compared to clopidogrel. In patients treated with PCI, it also reduces the rate of stent thrombosis.

Dosage and administration : Initiate Ticagrelor treatment with a 180mg (two 90mg tablets) loading dose and continue treatment with 90mg twice daily. After the initial loading dose of aspirin (usually 325mg) use Ticagrelor with a daily maintenance dose of aspirin of 75-100mg. It can be administered with or without food. A patient who misses a dose of Ticagrelor should take one 90mg tablet (their next dose) at its scheduled time. Or, as directed by the registered physician.

Contraindication : Ticagrelor is contraindicated in patients with active pathological bleeding such as peptic ulcer or intracranial hemorrhage. It is also contraindicated in patients with hypersensitivity to Ticagrelor or any component of the product.

Precautions : Ticagrelor increased the overall risk of bleeding (major & minor) to a somewhat greater extent than did clopidogrel. The increase was seen for non-CABG-related bleeding, but not for CABG-related bleeding.

Side effects : Bleeding is the most commonly reported adverse reaction. Others adverse effects include dyspnea, hypertension, fatigue, headache, back pain, dizziness, nausea, hypotension etc.

Use in Pregnancy and lactation : Pregnancy category C. There are no adequate data available for the use in pregnant women. It is not known whether ticagrelor or its active metabolites are excreted in human milk.

Use in Child : The safety and effectiveness in children have not been established.

Drug Interactions : Ticagrelor is predominantly metabolized by CYP3A4 and to a lesser extent by CYP3A5. So the use of strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, ritonavir, nelfinavir, indinavir, atazanavir and telithromycin) and potent inducers of CYP3A (e.g., rifampin, dexamethasone, phenytoin, carbamazepine and phenobarbital), simvastin, lovostin and digoxin should be avoided.

Overdose : Overdose of Ticagrelor may include gastrointestinal effects (nausea, vomiting, diarrhea).

Storage : Store below 30° C in a dry place.

Packing : Each box contains 1 x 14's tablets in blister pack.