TILDEX

TICAGRELOR INN

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

Pharmacology:
Ticagrelor, a cyclopentyltriazolopyrimidine, inhibitor of platelet activation and aggregation mediated by the P2Y12 ADP-receptor. Ticagrelor and its major metabolite reversibly interact with the platelet P2Y12 ADP-receptor to prevent signal transduction and platelet activation. Ticagrelor and its active metabolite are approximately equipotent.

Dosage And Administration:
Adult: In the management of ACS, initiate treatment with a 180 mg loading dose. Administer 90 mg twice daily during the first year after an ACS event. After one year administer 60 mg twice daily. A patient who misses a dose should take one tablet (their next dose) at its scheduled time. Do not administer with another oral P2Y12 platelet inhibitor. Use with a daily maintenance dose of aspirin of 75-100 mg. Pediatric Use: The safety and effectiveness of Ticagrelor in pediatric patients have not been established. Elderly: No overall differences in safety or effectiveness were observed between elderly and younger patients

Contraindications:
Contraindicated in patients with a history of intracranial hemorrhage (ICH) because of a high risk of recurrent ICH in this population, active pathological bleeding such as peptic ulcer or intracranial hemorrhage, in patients with hypersensitivity (e.g., angioedema) to Ticagrelor or any component of the product.

Warning And Precaution:
Avoid use of Ticagrelor in patients with severe hepatic impairment. Severe hepatic impairment is likely to increase serum concentration of Ticagrelor.Discontinuation of Ticagrelor will increase the risk of myocardial infarction, stroke, and death. If Ticagrelor must be temporarily discontinued (e.g., to treat bleeding or for significant surgery), restart it as soon as possible. When possible, interrupt therapy with Ticagrelor for five days prior to surgery that has a major risk of bleeding. Resume Ticagrelor as soon as hemostasis is achieved.

Side Effects:
Most common adverse reactions are bleeding and dyspnea

Use in Pregnancy and Lactation:
Pregnancy: Pregnancy Category C. There are no or limited amount of data from the use of Ticagrelor in pregnant women. Ticagrelor is not recommended during pregnancy. Lactation: There are no data on the presence of Ticagrelor or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Ticagrelor and its metabolites were present in rat milk at higher concentrations than in maternal plasma. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Breastfeeding is not recommended during treatment with Ticagrelor.

Drug Interaction:
Strong CYP3A inhibitors substantially increase Ticagrelor exposure and so increase the risk of dyspnea, bleeding, and other adverse events. Avoid use of strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin) Strong CYP3A inducers

substantially reduce Ticagrelor exposure and so decrease the efficacy of Ticagrelor. Avoid use with strong inducers of CYP3A (e.g., rifampin, phenytoin, carbamazepine and phenobarbital) Use of Ticagrelor with aspirin maintenance doses above 100 mg reduced the effectiveness of Ticagrelor As with other oral P2Y12 inhibitors, co-administration of opioid agonists delay and reduce the absorption of Ticagrelor and its active metabolite presumably because of slowed gastric emptying. Consider the use of a parenteral anti-platelet agent in acute coronary syndrome patients requiring co-administration of morphine or other opioid agonists. Ticagrelor increases serum concentrations of simvastatin and lovastatin because these drugs are metabolized by CYP3A4. Avoid simvastatin and lovastatin doses greater than 40 mg. Ticagrelor inhibits the P-glycoprotein transporter; monitor digoxin levels with initiation of or change in Ticagrelor therapy

Overdosage:
In case of drug overdose, contact a health care practitioner, hospital emergency department.

Storage:
Store in a cool (below 30°C) and dry place, protected from light and moisture. Keep out of the reach of children.

Packing:
Each box contains 1 x 10 tablets in Alu-Alu blister pack.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.