Abridged Prescribing Information:

Abridged prescribing information for Ticagrelor

Active Ingredient: Ticagrelor 90 tablets contain ticagrelor 90 mg, respectively. **Indication:** For the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute coronary syndromes (ACS) [unstable angina, non ST elevation Myocardial infarction (NSTEMI) & STEMI] including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). **Dosage & Administration:** Dosing: Initiate treatment with 180 mg oral loading dose following an ACS event. Continue treatment with 90 mg twice daily during the first year after an ACS event. After one year, administer 60 mg ticagrelor twice daily. Do not administer ticagrelor with another oral P2Y12 platelet inhibitor. Use ticagrelor with a daily maintenance dose of aspirin of 75-100 mg. A patient who misses a dose of ticagrelor should take one tablet (their next dose) at its scheduled time. Administration: For patients who are unable to swallow tablets whole, ticagrelor tablets can be crushed, mixed with water and drunk. The mixture can also be administered via a nasogastric tube (CH8 or greater). **Contraindications:** History of intracranial hemorrhage. Active pathological bleeding, such as peptic ulcer or intracranial hemorrhage. Hypersensitivity to ticagrelor or any component of the product. **Warnings & Precautions:** General risk of bleeding, use of ticagrelor with aspirin maintenance dose of 75 to 100 mg, mild to moderate dyspnea which often resolved during continued treatment, Bradyarrhythmias, sever hepatic impairment. **Pregnancy & Lactation:** Pregnancy: Available data from case reports with ticagrelor use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes although in animal studies, ticagrelor caused structural abnormalities Nursing mothers: Discontinue drug or nursing. **Interaction:** Strong CYP3A Inhibitors: Avoid use of strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir and telithromycin), Strong CYP3A Inducers: 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, co-administration of opioid agonists delay and reduce the absorption of ticagrelor and its active metabolite **Adverse Reactions:** Bleeding, including life-threatening and fatal bleeding, dyspnea, nausea, dizziness, bradycardia, syncope. **Use in special populations:** Hepatic Impairment: No dosage adjustment is needed in patients with mild hepatic impairment. Avoid use of ticagrelor in patients with severe hepatic impairment. Renal Impairment: No dosage adjustment is needed in patients with renal impairment **Overdose:** Overdose following ticagrelor administration may result in bleeding complications. If bleeding occurs, appropriate supportive measures should be taken. There is currently no known treatment to reverse the effects of ticagrelor, and ticagrelor is not dialyzable. This is abridged prescribing information for Ticagrelor. It is recommended to refer to the full prescribing information before prescribing.

(For details, please refer full prescribing information)

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