

Only for the use of Medical Professional

Acora[®]

Ticagrelor

Description

Acora[®] is a preparation of Ticagrelor. It is a cyclopentyltriazolopyrimidine which is a reversible platelet aggregation inhibitor. Ticagrelor reversibly binds with the platelet P2Y₁₂ adenosine diphosphate (ADP) receptors and thereby inhibits signal transduction and platelet aggregation. In contrast to the other antiplatelet drugs, Ticagrelor has a binding site different from ADP, making it an allosteric antagonist, and the blockage is reversible. Moreover, the drug does not need hepatic activation, which might work better for patients with genetic variants regarding the enzyme CYP2C19.

Indication

Ticagrelor is indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction).

Ticagrelor has been shown to reduce the rate of a combined endpoint of cardiovascular death, myocardial infarction, or stroke compared to clopidogrel. The difference between treatments was driven by CV death and MI with no difference in stroke. In patients treated with PCI, it also reduces the rate of stent thrombosis.

Dosage and administration

Treatment should be initiated with Ticagrelor 180 mg (two 90 mg tablets) with an initial dose of Aspirin (325 mg) as a loading dose. Then treatment should be continued with Ticagrelor 90 mg twice daily with Aspirin (75-100 mg) as a maintenance dose.

A patient who misses a dose of Ticagrelor should take one 90 mg tablet (their next dose) at its scheduled time.

Use in pregnancy & lactation

Ticagrelor is a Pregnancy Category C. There are no adequate and well-controlled studies of Ticagrelor use in pregnant women. Ticagrelor should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether Ticagrelor or its active metabolites are excreted in human milk. Therefore, Ticagrelor is not recommended for use in lactating mother.

Side effects

The most common side effects are bleeding and dyspnea. Other side effects are headache, back pain, nausea, dizziness, cough, hypotension, fatigue, and atrial fibrillation.

Contraindications

Ticagrelor is contraindicated in patients with hypersensitivity (e.g. angioedema) to Ticagrelor or any component of the product. It is also contraindicated in patients with a history of intracranial hemorrhage (ICH) because of a high risk of recurrent ICH in this population and patients with active bleeding disorders (e.g., peptic ulcer and intracranial hemorrhage). Ticagrelor is contraindicated in patients with severe hepatic impairment because of a probable increase in exposure, and it has not been studied in these patients. Severe hepatic impairment increases the risk of bleeding because of reduced synthesis of coagulation proteins.

Precautions

Caution should be exercised in patients with bleeding disorder as because like other antiplatelet agents, Ticagrelor increases the risk of bleeding. Consider the risks and benefits of treatment, noting the probable increase in exposure to ticagrelor in case of moderate hepatic impairment. Premature discontinuation increases the risk of myocardial infarction, stent thrombosis, and death.

Drug interaction

Ticagrelor is predominantly metabolized by CYP3A4 and to a lesser extent by CYP3A5. Ticagrelor is also a p-glycoprotein (P-gp) substrate. Patients receiving more than 40 mg per day of simvastatin or lovastatin may be at increased risk of statin-related adverse effects. Monitor digoxin levels with initiation of or any change in Ticagrelor. Use of Ticagrelor with aspirin maintenance doses above 100 mg reduced the effectiveness of Ticagrelor.

Overdose

There is currently no known treatment to reverse the effects of Ticagrelor, and Ticagrelor is not expected to be dialyzable. Treatment of overdose should follow the local standard medical practice. Bleeding is the expected pharmacologic effect of overdosing. If bleeding occurs, appropriate supportive measures should be taken. Other effects of an overdose may include gastrointestinal effects (nausea, vomiting, and diarrhea) or ventricular pauses. Monitor the ECG.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Acora[®] tablet: Each coated tablet contains Ticagrelor INN 90 mg.

Package quantities

Acora[®] tablet: Carton of 10 tablets in blister pack.

® Registered Trade Mark



ACI Limited

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