

AGGRITOR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for AGGRITOR [Tirofiban Hydrochloride I.V. Injection 5mg/100ml] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Reversible non-peptide antagonist of fibrinogen binding to the GP IIb/IIIa receptor, the major platelet surface receptor involved in platelet aggregation.

INDICATION: AGGRITOR, in combination with heparin and ASA is indicated in the management of patients with unstable angina or non-Q-wave myocardial infarction, including patients who may subsequently undergo PTCA, to decrease the rate of refractory ischemic conditions, new myocardial infarction and death.

DOSAGE AND ADMINISTRATION: In most patients, tirofiban hydrochloride should be administered intravenously, at an initial rate of 0.4 mcg/kg/min for 30 minutes and then continued at 0.1 mcg/kg/min. Patients with severe renal insufficiency (creatinine clearance <30 mL/min) should receive half the usual rate of infusion. **Use with Aspirin and Heparin:** In the clinical studies, patients received aspirin, unless it was contraindicated, and heparin. Tirofiban hydrochloride and heparin can be administered through the same intravenous catheter.

CONTRAINDICATION: Known hypersensitivity to any component of the product; active internal bleeding; History of bleeding diathesis (previous 30 days); intracranial hemorrhage or neoplasm, arteriovenous malformation, or aneurysm, thrombocytopenia, hemorrhagic stroke, aortic dissection, who developed thrombocytopenia following prior exposure to AGGRITOR; coagulopathy; platelet disorder; history of thrombocytopenia, stroke (within 30 days); major surgical procedure or severe physical trauma within the previous month; history or symptoms suggestive of aortic dissection; severe uncontrolled hypertension; concomitant use of another GP IIb/IIa inhibitor; acute pericarditis; Cirrhosis/clinically significant liver disease; recent epidural procedure; angina (precipitated by provoking factors like arrhythmia, severe anemia, hyperthyroidism or hypotension)

WARNINGS & PRECAUTIONS: Exercise caution while use in patients taking drugs affecting hemostasis, patients with recent bleedings (less than 1 year), platelet count < 150,00 cells/mm³; history of cerebrovascular disease within 1 year; hemorrhagic retinopathy and chronic hemodialysis.

DRUG INTERACTIONS: Interacts with aspirin and heparin (increase bleeding); Patients who received levothyroxine or omeprazole along with Tirofiban had a higher rate of clearance of Tirofiban.

ADVERSE REACTIONS: Bleeding (oozing or mild in nature) including intracranial bleeding, retroperitoneal bleeding, gastrointestinal and genitourinary bleeding; pulmonary (alveolar) hemorrhage; spinal-epidural hematoma; bleeding complications; edema/swelling, pain in pelvic region, vasovagal reaction, bradycardia, coronary artery dissection, leg pain, dizziness, sweating, nausea, fever, headache, allergic reactions (anaphylaxis), decrease hemoglobin/hematocrit, severe thrombocytopenia.

MARKETED BY:



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(Additional information is available on request)