EPTIBIND 75

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.

Abbreviated Prescribing information for EPTIBIND 75 Eptifibatide 0.75 mg (Eptifibatide Injection)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Eptifibatide reversibly inhibits platelet aggregation by preventing the binding of fibrinogen, von Willebrand factor, and other adhesive ligands to GP IIb/IIIa. When administered intravenously, eptifibatide inhibits ex-vivo platelet aggregation using adenosine diphosphate (ADP) and other agonists in a dose- and concentration-dependent manner. Platelet aggregation inhibition is reversible following cessation of the eptifibatide infusion; this is thought to result from dissociation of eptifibatide from the platelet.

DOSAGE AND ADMINISTRATION: As directed by physician**.**

The safety and efficacy of eptifibatide has been established in clinical studies that employed concomitant use of heparin and aspirin. Different dose regimens of eptifibatide were used in the major clinical studies

CONTRAINDICATION:

- Hypersensitivity to Eptifibatide or to any component of the formulation.
- Evidence of gastrointestinal bleeding, gross genitourinary bleeding or other active abnormal bleeding within the previous 30 days of treatment.
- History of stroke within 30 days or any history of hemorrhagic stroke.
- Known history of intracranial disease (neoplasm, arteriovenous malformation, aneurysm)
- Major surgery or severe trauma within past 6 weeks.
- A history of bleeding diathesis
- Thrombocytopaenia (<1,00,000 cells/mm3)
- Severe hypertension (systolic blood pressure > 200 mm Hg or diastolic blood pressure > 110 mm Hg) not adequately controlled on antihypertensive therapy
- Prothrombin time >1.2 times control, or international Normalized Ratio (INR) ≥ 2.0
- Severe renal impairment (creatinine clearance <30 mL/min) or dependency on renal dialysis.
- Clinically significant hepatic impairment
- Concomitant or planned administration of another parenteral GP IIb/IIIa inhibitor

WARNINGS & PRECAUTIONS: Bleeding, Arterial procedures, Thrombocytopaenia, Heparin administration. Monitoring of Laboratory values, Immunogenicity, Renal Insufficiency, Carcinogenesis, Mutagenesis, Impairment of Fertility, Warfarin and dipyridamole,

DRUG INTERACTION: *Warfarin and dipyridamole :* Eptifibatide did not increase the risk of major and minor bleeding associated with concomitant use of warfarin and dipyridamole.

Eptifibatide and thrombolytic agents: Data are limited on the use of eptifibatide in patients receiving thrombolytic agents. There was no consistent evidence that eptifibatide increased the risk of major or minor bleeding associated with tissue plasminogen activator in either a PCI or an acute myocardial infarction study; Eptifibatide appeared to increase the risk of bleeding when administered with streptokinase in an acute myocardial infarction study. The combination of reduced dose tenecteplase and eptifibatide compared to placebo and eptifibatide significantly increased the risk of both major and minor bleeding when administered concomitantly in an acute ST-elevation myocardial infarction study. In an acute myocardial infarction study

involving 181 patients it is reported that, eptifibatide (in regimens up to a bolus injection of 180 microgram/kg, followed by an infusion up to 2 microgram/kg/min for up to 72 hours) was administered concomitantly with streptokinase (1.5 million units over 60 minutes). At the highest infusion rates (1.3 microgram/kg/min and 2.0 microgram/kg/min) studied, eptifibatide was associated with an increased incidence of bleeding and transfusions compared to the incidence seen when streptokinase was given alone.

ADVERSE REACTIONS: The majority of undesirable effects experienced by patients treated with eptifibatide were generally related to bleeding, Thrombocytopenia, Allergic Reactions, cardiovascular envents, cerebral, GI, and pulmonary hemorrhage. Fatal bleeding events have been reported. Acute profound thrombocytopenia has been reported.

MARKETED BY:

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(Additional information is available on request)