

STYPTOVIT TX

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
abbreviated prescribing information for STYPTOVIT TX (Etamsylate & Tranexamic Acid Tablets)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: *Etamsylate:* Etamsylate is a synthetic antihaemorrhagic and angioprotective drug acting on the first step of haemostasis (endothelium-platelet interaction). By improving platelet adhesiveness and restoring capillary resistance, it is able to reduce bleeding time and blood losses. Etamsylate has no vasoconstrictor action, it does not influence fibrinolysis nor modify the plasma coagulation factors. *Tranexamic Acid:* Tranexamic acid is an antifibrinolytic compound which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non-competitive inhibitor of plasmin. The inhibitory effect of tranexamic acid in plasminogen activation by urokinase has been reported to be 6-100 times and by streptokinase 6-40 times greater than that of aminocaproic acid. The antifibrinolytic activity of tranexamic acid is approximately ten times greater than that of aminocaproic acid.

INDICATION: Styptovit TX tablets are indicated for the treatment of abnormal blood loss due to menorrhagia, local fibrinolysis and intra operative/post-operative haemorrhage.

DOSAGE AND ADMINISTRATION: As directed by physician. Oral Administration

CONTRAINDICATION: *Etamsylate:* Acute porphyria. Hypersensitivity to the active substance or to any of the excipients. Bronchial asthma, proven hypersensitivity to sulphites. *Tranexamic Acid:* Hypersensitivity to the active substance or to any of the excipients. Severe renal failure because of risk of accumulation. Active thromboembolic disease. History of venous or arterial thrombosis Fibrinolytic conditions following consumption coagulopathy History of convulsions.

WARNINGS & PRECAUTIONS: *Etamsylate:* If Styptovit E is administered for a reduction of excessive and/or prolonged menstrual haemorrhages, and no improvement is observed, possible pathological causes should be looked for and excluded. *Tranexamic Acid:* In case of haematuria of renal origin (especially in haemophilia), there is a risk of mechanical anuria due to formation of a ureteral clot. In the long-term treatment of patients with hereditary angioneurotic oedema, regular eye examinations (e.g. visual acuity, slit lamp, intraocular pressure, and visual fields) and liver function tests should be performed. Patients with irregular menstrual bleeding should not use Tranexamic Acid. Extra care in patients receiving oral contraceptives because of the increased risk of thrombosis. Patients with a previous thromboembolic event and a family history of thromboembolic disease. The blood levels are increased in patients with renal insufficiency. Therefore a dose reduction is recommended. Patients who experience visual disturbance should be withdrawn from treatment.

DRUG INTERACTIONS: *Etamsylate:* No interaction is known up to now. *Tranexamic Acid:* Tranexamic Acid will counteract the thrombolytic effect of fibrinolytic preparations.

ADVERSE REACTIONS: *Etamsylate:* Gastralgia, diarrhea, nausea, headache, skin rash. The allergic reactions may lead to anaphylactic shock and cause life-threatening asthma attacks. *Tranexamic Acid:* Hypersensitivity reactions anaphylaxis, nausea, vomiting, diarrhoea, thromboembolic events, impaired colour vision, visual disturbances, retinal/artery occlusion

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)