XAMIC INJECTION For the Use of a Specialist Only

Abbreviated Prescribing information for **XAMIC INJECTION** [Tranexamic Acid Injection 100 mg/ml] complete prescribing information available at www.torrentpharma.com PHARMACOLOGICAL PROPERTIES: Tranexamic acid produces an anti-fibrinolytic effect by competitively inhibiting the activation of plasminogen to plasmin. It is also a weak noncompetitive inhibitor of plasmin. INDICATION: Xamic injection is used for the treatment of excessive bleeding in patients with hemophilia during and following tooth extraction. It is used for local fibrinolysis and general fibrinolysis. DOSAGE AND ADMINISTRATION: For intravenous use only. Immediately before dental extraction in patients with hemophilia, administer 10 mg per kg body weight. Local Fibrinolysis: recommended standard dose is 5-10ml (500-1000mg) by slow intravenous injection (1 ml/min), three times daily. General Fibrinolysis: In disseminated intravascular coagulation with predominant activation of the fibrinolytic system, a single dose of 10ml (1g) is sufficient to control bleeding. **CONTRAINDICATION:** It is contraindicated in patients with active intravascular clotting, acquired defective color vision, subarachnoid hemorrhage. It is contraindicated with use of hormonal contraception and in patients with a history of thromboembolic disease. WARNINGS & PRECAUTIONS: For patients to be treated continually for longer than several days, an ophthalmological examination, including visual acuity, color vision, eye-ground and visual fields, is advised, before commencing and at regular intervals during the course of treatment. The dose should be reduced in patients with renal insufficiency. Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. DRUG INTERACTIONS: It may further exacerbate the increased thrombotic risk associated with combination hormonal contraceptives. Concomitant therapy with tissue plasminogen activators may decrease the efficacy of both Tranexamic acid and tissue plasminogen activators. It is not recommended for women taking either Factor IX complex concentrates. Exercise caution when prescribing it to women with acute promyelocytic leukemia taking all-trans retinoic acid. ADVERSE REACTIONS: Gastrointestinal disturbances (nausea, vomiting, diarrhea), allergic dermatitis, giddiness, hypotension, thromboembolic events (e.g., deep vein thrombosis, pulmonary embolism, cerebral thrombosis, acute renal cortical necrosis, and central retinal artery and vein obstruction), convulsion and chromatopsia.

MARKETED BY:



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IN/ XAMIC INJECTION 100 mg/ml/MAY-2016/01/ABPI

(Additional information is available on request)