XAMIC 500

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

Abbreviated Prescribing information for XAMIC INJECTION [Tranexamic Acid Tablets I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Tranexamic acid exerts an anti-haemorrhagic activity by inhibiting the fibrinolytic properties of plasmin.A complex involving tranexamic acid, plasminogen is constituted; the tranexamic acid being linked to plasminogen when transformed into plasmin**.**

INDICATIONS: Xamic injection is used for the treatment of Haemorrhage or risk of haemorrhage in increased fibrinolysis of hereditary angioneurotic oedema**.**

DOSAGE AND ADMINISTRATION: Following surgery, a dose of 25 mg per kg body weight may be given orally three or four times daily for 2 to 8 days. Tranexamic acid can be administered entirely orally; 25 mg per kg body weight 3 to 4 times a day beginning one day prior to surgery. In the case of patients with moderate to severe impaired renal function, the dosages need to be reduced. For serum creatinine 120 to 250 (1.36 to 2.83mg/dl), the dosage is 15mg/kg BID. For serum creatinine 250 to 500 (2.83 to 5.66 mg/dl) the dosage is 15mg/kg daily. For serum creatinine > 500 (>5.66 mg/dl) the dosage is 15mg/kg every 48 hours OR 7.5mg/kg every 24. Tranexamic acid is indicated for women of reproductive age and is not intended for use in premenarcheal girls. Tranexamic acid is indicated for women of reproductive age and is not intended for use by postmenopausal women.

CONTRAINDICATION: Hypersensitivity to the active substance or any of the excipients. For patients with severe renal impairment because of risk of accumulation, active thromboembolic disease, history of venous or arterial thrombosis, fibrinolytic conditions following consumption coagulopathy and history of convulsions.

WARNINGS & PRECAUTIONS: 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, visual fields) and liver function tests should be performed. Patients with irregular menstrual bleeding should not use Xamic 500 until the cause of irregular bleeding has been established. Tranexamic acid should be administered with 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 (patients with thrombophilia) should use Xamic 500 only if there is a strong medical indication and under strict medical supervision. The blood levels are increased in patients with renal insufficiency. Therefore, a dose reduction is recommended. The use of tranexamic acid in cases of increased fibrinolysis due to disseminated intravascular coagulation is not recommended. Patients who experience visual disturbance should be withdrawn from treatment.

DRUG INTERACTIONS: Xamic 500 will counteract the thrombolytic effect of fibrinolytic preparations.

ADVERSE REACTIONS: Hypersensitivity reactions including anaphylaxis, colour vision disturbances, retinal/artery occlusion, thromboembolic events, arterial or venous thrombosis at any sites, digestive effects such as nausea, vomiting and diarrhoea, may occur but disappear when the dosage is reduced., allergic skin reactions, and convulsions/seizures, particularly in cases of misuse.

MARKETED BY:

Torrent Pharmaceuticals Limited.
IN/XAMIC 500mg/Oct-2022/03/ABPI
(Additional information is available on request)