XAMIC INJECTION

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

Abbreviated Prescribing information for XAMIC INJECTION [Tranexamic Acid Injection 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: Xamic Injection is for intravenous use only**.** Do not use the injection if the contents are not clear or show particulate matter. *Impaired renal function*-In the case of patients with moderate to severe impaired renal function, the dosages need to be reduced. For *Local Fibrinolysis***,** the recommended standard dose is 5-10ml (500-1000mg) by slow intravenous injection (1 ml/min), three times daily. *Children***:** According to body weight (10mg/kg body wt/ 2-3 times daily). *General Fibrinolysis*- In disseminated intravascular coagulation with predominant activation of the fibrinolytic system, usually a single dose of 10ml (1g) is sufficient to control bleeding. For neutralisation of thrombolytic therapy; 10mg/kg body wt by slow intravenous injection.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Acute venous or arterial thrombosis. Fibrinolytic conditions following consumption coagulopathy except in those with predominant activation of the fibrinolytic system with acute severe bleeding. Severe renal impairment (risk of accumulation). History of convulsions. Intrathecal and intraventricular injection, intracerebral application (risk of cerebral oedema and convulsions.

WARNINGS & PRECAUTIONS: Attention should be paid to possible visual disturbances including visual impairment, vision blurred, impaired colour vision and if necessary, the treatment should be discontinued. In case of haematuria from the upper urinary tract, there is a risk for urethral obstruction. In patients with a history of thromboembolic diseases or in those with increased incidence of thromboembolic events in their family history (patients with a high risk of thrombophilia), tranexamic acid should only be administered if there is a strong medical indication after consulting a physician. Patients with disseminated intravascular coagulation (DIC) should in most cases not be treated with tranexamic acid. If tranexamic acid is given it must be restricted to those in whom there is predominant activation of the fibrinolytic system with acute severe bleeding.

DRUG INTERACTIONS: There is a theoretical risk of increased thrombus-formation potential, such as with oestrogens. Alternatively, the antifibrinolytic action of the drug may be antagonised with thrombolytic drugs.

ADVERSE REACTIONS: Hypersensitivity reactions including anaphylaxis, convulsions/seizures particularly in case of misuse, visual disturbances including impaired colour vision, malaise with hypotension, with or without loss of consciousness (generally following a too fast intravenous injection, exceptionally after oral administration), arterial or venous thrombosis at any sites, diarrhoea, vomiting, nausea, and dermatitis allergic.

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/XAMIC Injection 500mg/Aug-2019/03/ABPI

(Additional information is available on request)