For Effective Prevention and Treatment of Haemorrhages

Unixam®

Tranexamic acid

UNIXAM® 100mg

CODAL-SYNTO

Summary of the SPC for Unixam®

Name of the Medicinal Product:	Unixam®
Qualitative and Quantitative Composition:	Each 100mg/ml ampoule contains 5ml or 10ml of an aqueous solution containing 100mg/ml of tranexamic acid.
Pharmaceutical Form:	Solution for injection
Therapeutic Indications:	Prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one year's old. Menorrhagia and metrorrhagia; Gastrointestinal bleeding; Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract; Ear Nose Throat surgery; Gynaecological surgery or disorders of obstetric origin; Thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery; Management of haemorrhage due to the administration of a fibrinolytic agent.
Posology and Method of Administration:	Adults: Standard treatment of local fibrinolysis: 0.5 g to 1g tranexamic acid by slow intravenous injection (= 1 ml/minute) two to three times daily. Standard treatment of general fibrinolysis: 1 g tranexamic acid by slow intravenous injection (= 1 ml/minute) every 6 to 8 hours, equivalent to 15 mg/kg BW. Renal impairment: For patient with mild to moderate renal impairment, the dosage of tranexamic acid should be reduced according to the serum creatinine level. Paediatric population: In children from 1 year, for current approved indications, the dosage is in the region of 20 mg/kg/day.
Contra-indications:	Hypersensitivity; 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; History of convulsions; Intrathecal and intraventricular injection, intracerebral application
Special Warnings and Precautions for Use:	Tranexamic acid should not be administered by the intramuscular route; Coronary artery bypass graft surgery; Visual disturbances; Haematuria from the upper urinary tract; History of thromboembolic diseases; Increased incidence of thromboembolic events in their family history; Patients receiving oral contraceptives; Disseminated intravascular coagulation.
Interactions with Other Medicinal Products and Other Forms of Interaction:	Anticoagulants; Medicinal products that act on haemostasis; Oestrogens; The antifibrinolytic action of the drug may be antagonised with thrombolytic drugs.
Pregnancy and Lactation:	Tranexamic acid should be used throughout pregnancy only if the expected benefit justifies the potential risk. Breastfeeding is not recommended.
Undesirable effects:	Dermatitis allergic; Diarrhoea, vomiting, nausea; Convulsions particularly in case of misuse; Visual disturbances including impaired colour vision; Malaise with hypotension, with or without loss of consciousness, arterial or venous thrombosis at any sites; Hypersensitivity reactions including anaphylaxis.
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MAH: Codal Synto Ltd.