For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Pause

Injection

Tranexamic Acid Injection BP

For I.V. Injection only

COMPOSITION

Each 5 ml ampoule contains:
Tranexamic Acid BP 500 mg
Water for Injection BP q.s.

DESCRIPTION

Tranexamic acid is an antifibrinolytic agent. Chemically it is designated as trans-4-(aminomethyl) cyclohexanecarboxylic acid. It has empirical formula of $C_8H_{15}NO_2$ and molecular weight of 157.2.

CLINICAL PHARMACOLOGY

Mechanism of action

Tranexamic acid competitively inhibits the activation of plasminogen to plasmin. At much higher concentrations, it is also a weak noncompetitive inhibitor of plasmin. Antifibrinolytic activity is related mainly to a reversible complex formation with a modified plasminogen and associated conformational changes of this proenzyme.

Pharmacokinetics

Tranexamic acid is very weakly bound to plasma proteins (about 3%). It is widely distributed throughout the body. Plasma half-life is about 2 hours. Urinary excretion is the main route of elimination (largely excreted as unchanged) via glomerular filtration.

INDICATIONS

Prevention and treatment of haemorrhages due to general or local fibrinolysis in adults and children from one year.

Specific indications include:

- Haemorrhage caused by general or local fibrinolysis such as:
- Menorrhagia and metrorrhagia,
- Gastrointestinal bleeding,
- Haemorrhagic urinary disorders, further to prostate surgery or surgical procedures affecting the urinary tract,
- Ear Nose Throat surgery (adenoidectomy, tonsillectomy, dental extractions),
- 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.

DOSAGE AND ADMINISTRATION

The administration is strictly limited to slow intravenous injection.

Local fibrinolysis: The recommended standard dose is 5-10 ml (500-1000 mg) by slow intravenous injection (1 ml/min), two to three times daily.

General fibrinolysis: 1 g (2 ampoules) tranexamic acid by slow intravenous injection (1 ml/minute) every 6 to 8 hours, equivalent to 15 mg/kg body weight.

Children: In children from 1 year, according to body weight (20 mg/kg body weight /day).

Elderly patients: No reduction in dosage is necessary unless there is evidence of renal failure.

Renal impairment: In patients with renal insufficiency because of the risk of accumulation, the dose should be reduced according to the following table:

Serum Creatinine (micromol/L)	Dose by IV Route	Dose Frequency
120-250 (1.36 to 2.83 mg/dL)	10 mg/kg	Twice daily
250-500 (2.83 to 5.66 mg/dL)	10 mg/kg	Every 24 hour
> 500 (>5.66 mg/dL)	5 mg/kg	Every 24 hour

Hepatic impairment: No dose adjustment is required in patients with hepatic impairment.

For IV infusion, tranexamic acid solution for injection may be mixed with the following solutions: isotonic sodium chloride; isotonic glucose; 20% fructose; 10% invertose; dextran 40; dextran 70; ringer's solution. Tranexamic acid solution for injection may be mixed with heparin. Tranexamic acid is a synthetic amino acid, and should NOT be mixed with solutions containing penicillin.

CONTRAINDICATIONS

- Tranexamic acid is contraindicated in patients with history of thromboembolic disease as they may be at risk of venous or arterial thrombosis.
- In patients with acquired defective color vision, since this prohibits measuring one endpoint that should be followed as a measure of toxicity.
- In patients with subarachnoid hemorrhage. Anecdotal experience indicates that cerebral edema and cerebral infarction may be caused by tranexamic acid in such patients.
- In patients with active intravascular clotting.
- History of convulsions

VIN'S
13218

Front

WARNINGS

- Intravenous injections should be given very slowly. Tranexamic acid should not be administered by the intramuscular route.
- For patients who are 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. Tranexamic acid should be discontinued if changes in examination results are found.
- Convulsions have been reported in association with tranexamic acid treatment, particularly in patients receiving tranexamic acid during cardiovascular surgery and in patients inadvertently given tranexamic acid into the neuraxial system.

PRECAUTIONS

- Ureteral obstruction due to clot formation in patients with upper urinary tract bleeding has been reported in patients treated with tranexamic acid.
- Patients with disseminated intravascular coagulation (DIC), who require treatment with tranexamic acid, must be under strict supervision of a physician experienced in treating this disorder.
- Venous and arterial thrombosis or thromboembolism has been reported in patients treated with tranexamic acid. In addition, cases of central retinal artery and central retinal vein obstruction have been reported.
- Patients with a previous history of thromboembolic disease may be at increased risk for venous or arterial thrombosis.
- Tranexamic acid should not be administered concomitantly with Factor IX Complex concentrates or Anti-inhibitor Coagulant concentrates, as the risk of thrombosis may be increased.
- Tranexamic acid may cause dizziness and therefore may influence the ability to drive or use machines.

USE IN SPECIAL POPULATIONS

Pregnancy

Pregnancy Category B.

There are no adequate and well-controlled studies in pregnant women. However, tranexamic acid is known to pass the placenta and appears in cord blood at concentrations approximately equal to maternal concentration. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood. Caution should be exercised when tranexamic acid is administered to a nursing woman.

Pediatric Use

The drug has limited efficacy and safety in pediatric patients. The efficacy and safety of tranexamic acid in children undergoing cardiac surgery have not been fully established. Dosing instructions for adults can be used for pediatric patients needing tranexamic acid therapy.

Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Gastrointestinal disorders (nausea, vomiting, and diarrhea) may occur but disappear when the dosage is reduced. Allergic dermatitis, giddiness, and hypotension have been reported occasionally. Rare cases of thromboembolic events (e.g., deep vein thrombosis, pulmonary embolism, cerebral thrombosis, acute renal cortical necrosis, and central retinal artery and vein obstruction) have been reported. Hypersensitivity reactions including anaphylaxis, convulsion, chromatopsia, and visual impairment have also been reported.

DRUG INTERACTIONS

No studies of interactions between tranexamic acid and other drugs have been conducted.

OVERDOSAGE

Symptoms of overdosage may be nausea, vomiting, orthostatic symptoms and/or hypotension. Management of overdose should be supportive.

STORAGE :

Store in a dry & dark place, below 25°C.
Before using, check for absence of sediments.

PRESENTATION :

5 ampoules of 5 ml each.

Manufactured by :

Emcure
PHARMACEUTICALS LTD.
Hinjawadi, Pune - 411 057, INDIA.
At : J-174, J-168, J-168/1 MIDC,
Tarapur, Boisar, Dist. Thane - 401 506, India.

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Back

Product	Pause	**New / Revised A/W**	Revised A/W	**FDA Lic. Availability**	Avail. from
Dosage form	Injection	**Reason for change**	Editorial changes	**Proof 1**	21.04.2017
Therapeutic Category	Antifibrinolytic	**Colour Scheme**	Black	**Corrections of Proof 1**	Editorial changes
Item	Senegal Export Pack Insert A/W	**Pantone Shades**	N.A.	**Proof 2**	24.04.2017
Dimension	L. 62 x H. 208 mm (Folded 62 x 26 mm)	**Total No. of Colours**	1	**Corrections of Proof 2**	Editorial changes
Substrate	Super white maplitho paper (J. K. Mill)	**Special Effect (if any)**	N.A.	**Proof 3**	26.04.2017
Specification	60 GSM	**Item Code**	510005096SN02	**Corrections of Proof 3**	Editorial changes
Printing Area	B/B	**Marketing Division**	Emcure Export	**Final**	13.02.2018
Item Style	N.A.	**Design / Colour Approved on**	N.A.	**A/W Checked by**	PMD Cell
A/W Proportion	Same Size	**Vendor**	Dayal	**A/W Verified by**	Production / QC
Product Status	Emcure L/L Samrudh	**Country**	Senegal Export	**A/W Approved by**	Unit Head
Remark (If any) : Revised for editorial changes					
				Proof 4	27.04.2017