Rx Tranexamic Acid Injection IP 500 mg/5 mL

VERISTAT

500 mg

For Intravenous use only

COMPOSITION :

Each ml contains :

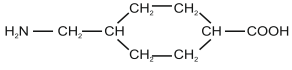
Tranexamic Acid IP 100 mg

Water for Injections IP q.s.

FORMULATION

Chemical Name: trans-4-(aminomethyl)cyclohexanecarboxylic acid

Structural Formula:



Empirical Formula: $C_8H_{15}NO_2$ Molecular Weight: 157.2

Tranexamic acid is a white crystalline powder. The aqueous solution for injection has a pH of 6.5 to 8.0.

Tranexamic Acid Injection - Clinical Pharmacology

Tranexamic acid is a competitive inhibitor of plasminogen activation, and at much higher concentrations, a noncompetitive inhibitor of plasmin, i.e., actions similar to aminocaproic acid. Tranexamic acid is about 10 times more potent in vitro than aminocaproic acid.

Tranexamic acid binds more strongly than aminocaproic acid to both the strong and weak receptor sites of the plasminogen molecule in a ratio corresponding to the difference in potency between the compounds. Tranexamic acid in a concentration of 1 mg per mL does not aggregate platelets in vitro.

Tranexamic acid, in concentrations as low as 1 mg per mL, can prolong the thrombin time. However, tranexamic acid in concentrations up to 10 mg per mL in blood showed no influence on the platelet count, the coagulation time, or other coagulation factors in whole blood or citrated blood from normal subjects.

The plasma protein binding of tranexamic acid is about 3% at therapeutic plasma levels and seems to be fully accounted for by its binding to plasminogen. Tranexamic acid does not bind to serum albumin.

After an intravenous dose of 1 g, the plasma concentration time curve shows a triexponential decay with a half-life of about 2 hours for the terminal elimination phase. The initial volume of distribution is about 9 to 12 liters. Urinary excretion is the main route of elimination via glomerular filtration. Overall renal clearance is equal to overall plasma clearance (110 to 116 mL/min), and more than 95% of the dose is excreted in the urine as unchanged drug. Excretion of tranexamic acid is about 90% at 24 hours after intravenous administration of 10 mg per kg body weight.

An antifibrinolytic concentration of tranexamic acid remains in different tissues for about 17 hours, and in the serum, up to seven or eight hours.

Tranexamic acid passes through the placenta. The concentration in cord blood after an intravenous injection of 10 mg per kg to pregnant women is about 30 mg per liter, as high as in the maternal blood. Tranexamic acid diffuses rapidly into joint fluid and the synovial membrane. In the joint fluid, the same concentration is obtained as in the serum. The biological half-life of tranexamic acid in the joint fluid is about three hours.

The concentration of tranexamic acid in a number of other tissues is lower than in blood. In breast milk, the concentration is about one hundredth of the serum peak concentration. Tranexamic acid concentration in cerebrospinal fluid is about one tenth of that of the plasma. The drug passes into the aqueous humor, the concentration being about one tenth of the plasma concentration.

Indications and Usage for Tranexamic Acid Injection

Tranexamic Acid Injection is indicated in patients with hemophilia for short-term use (two to eight days) to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction.

Contraindications

Tranexamic Acid Injection is contraindicated:

In patients with acquired defective color vision, since this prohibits measuring one endpoint that should be followed as a measure of toxicity (see WARNINGS).

In patients with subarachnoid hemorrhage. Anecdotal experience indicates that cerebral edema and cerebral infarction may be caused by Tranexamic Acid Injection in such patients.

In patients with active intravascular clotting.

In patients with hypersensitivity to tranexamic acid or any of the ingredients.

Warnings

Focal areas of retinal degeneration have developed in cats, dogs, and rats following oral or intravenous tranexamic acid at doses between 250 to 1600 mg/kg/day (6 to 40 times the recommended usual human dose) from 6 days to 1 year. The incidence of such lesions has varied from 25% to 100% of animals treated and was dose-related. At lower doses, some lesions have appeared to be reversible.

Drug Interactions

No studies of interactions between Tranexamic Acid Injection and other drugs have been conducted.

Overdosage

Cases of overdosage of Tranexamic Acid Injection have been reported. Based on these reports, symptoms of overdosage may be gastrointestinal, e.g., nausea, vomiting, diarrhea; hypotensive, e.g., orthostatic symptoms; thromboembolic, e.g., arterial, venous, embolic; neurologic, e.g., visual impairment, convulsions, headache, mental status changes; myoclonus; and rash.

Storage : Store in a cool, dry & dark place below 25°C. protect from light.

Shelf Life : 24 Months

HOW SUPPLIED

Tranexamic Acid Injection IP 500 mg/5 mL

5 Ampoules of 5 mL each packed in a carton.

Mfg. by:

Neoveritas Healthcare Pvt. Ltd.

(A WHO-GMP Certified)

At: Mauza Ogli, Suketi Road, Kala Amb,

District Sirmour - 173030 (H.P.)

Mktd. by:

Neoveritas Healthcare Pvt. Ltd.

Netaji Subhash Place,

Delhi - 110034, (INDIA)

Overseas Office

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