Fibrostat

Tranexamic acid BP

Presentation
Fibrostat 500 Cap.: Each capsule contains Tranexamic acid BP 500 mg.
Fibrostat 500 Injection: Each ampoule contains Tranexamic acid BP 500 mg.

Description
Tranexamic acid is an antifibrinolytic compound that competitively inhibits the activation of plasminogen to plasmin. It is a synthetic lysine amino acid derivative, which diminishes the dissolution of hemostatic fibrin by plasmin. In the presence of tranexamic acid, the lysine receptor binding sites of plasmin for fibrin are occupied, preventing binding to fibrin monomers, thus preserving and stabilizing fibrin's matrix structure. Its actions similar to aminocaproic acid but binds more strongly than aminocaproic acid to both the strong and weak receptor sites of the plasminogen molecule. So it is about 10 times more potent in vitro than aminocaproic acid.
Tranexamic acid is rapidly absorbed from the GIT with maximum serum levels are reached within 2-3 hours.

Indications
1. Fibrostat is indicated at the risk of hemorrhage in increased fibrinolysis or fibrinogenolysis that may occur in conditions:
- **Prostatectomy and bladder surgery**
- **Epistaxis**
- **Conisation of the cervix**
- **Management of dental extraction in patients with coagulopathies**
- **Menorrhagia**
- **Ulcerative colitis**
- **Haematuria**
- **Gastrointestinal haemorrhage**

2. General fibrinolysis as in prostatic and pancreatic cancer, after thoracic and other major surgery, in obstetrical complications such as abruptio placentae and post-partum haemorrhage, in leukaemia and liver diseases and in connection with thrombolytic therapy with streptokinase.

3. Hereditary angioneurotic oedema.

Dosage & Administration
Intravenous administration is necessary only if it is difficult to give adequate doses by mouth. The recommended standard dose is 1 to 1.5 gm or 5-10 ml by slow intravenous injection at a rate of 1 ml/min, two to three times daily. For the indications listed below the following doses are recommended.

Prostatectomy: Injection- 5 to 10 ml IV tid (the first injection being given during the operation) for the first three days after surgery. Capsule- 1.0 to 1.5 gm orally 3 to 4 times daily until macroscopic haematuria is no longer present. Menorrhagia: 1.0-1.5 gm orally three to four times daily for 3-4 days. Epistaxis: 1.5 gm orally tid for 4-10 days. Fibrostat injection may be applied topically to the nasal mucosa by soaking a gauze strip in the solution and then packing the nasal cavity Hematuria: 1.0-1.5 gm orally 2-3 times daily until macroscopic haematuria is no longer present. Conisation of the cervix: 1.5 gm orally 3 times a day for 12 to 14 days post-operatively. Dental surgery in patients with coagulopathies: Immediately before surgery, 10 mg/kg body-weight should be given intravenously. After surgery, 25 mg/kg body-weight are given orally tid for 6-8 days. General fibrinolysis: 1.0 gm (10 ml) IV 3-4 times daily. With fibrinolysis in conjunction with diagnosed, increased intravascular coagulation i.e. defibrillation syndrome, an anticoagulant such as heparin may be given with caution.

Hereditary angioneurotic oedema: 1.0-1.5 gm orally 2-3 times daily as intermittent or continuous treatment depending on whether the patient has prodromal symptoms or not. Children: In children, the dosage is 20 mg/kg/day
Patient with moderate to severe impaired renal function:
Serum Creatinine (µmol/L) Tranexamic Acid IV Dosage
120 to 250 (1.36 to 2.83 mg/dL) 10 mg/kg bid
250 to 500 (2.83 to 5.66 mg/dL) 10 mg/kg daily
> 500 (> 5.66 mg/dL) 10 mg/kg every 48 hours, 5 mg/kg every 24 hours

Side Effect
GIT disturbances (nausea, vomiting, diarrhea), hypotension (when intravenous injection is too rapid than 1 mL/min), thromboembolic events (deep vein thrombosis, pulmonary embolism, cerebral thrombosis, acute renal cortical necrosis, central retinal artery and vein obstruction) have been rarely reported.

Precaution
Patients with a high risk of thrombosis (a previous thromboembolic event and a family history of thromboembolic disease), prone to intravascular coagulation & patients with irregular menstrual bleeding should use it only if there is a strong medical indication and under strict medical supervision. As color vision disorder may occur during the course of treatment, regular eye examination should be performed.

Pharmaceutical precautions: Fibrostat injection should not be mixed with blood for transfusion or infusion solutions containing penicillin.

Contraindication
Subarachnoid hemorrhage, acquired defective color vision, cerebral edema and cerebral infarction, active intravascular clotting, hypersensitivity to tranexamic acid.

Use in Pregnancy & Lactation
Pregnancy: Tranexamic acid crosses the placenta. Clinical experience of use in pregnant women is limited. Animal studies have not supplied any evidence of an increased incidence of fetal damage. Lactation: Tranexamic acid is excreted into milk but it is not likely to influence the child at therapeutic doses.

Overdose
If overdosage is justified, initiate vomiting, then gastric lavage, charcoal therapy and symptomatic treatment. Maintain adequate diuresis. Symptoms may be Nausea, vomiting, dizziness, and headache happened.

Storage
Store at a cool (below 25°C) and dry place, protected from light and moisture. Keep out of the reach of children.

Commercial Packaging
Fibrostat 500 Capsule: Each box contains 2x10 capsules in blister strips.
Fibrostat 500 Injection: Each box contains 1x5 ampoules in blister strip.

Manufactured by:
Globe Pharmaceuticals Ltd.
Noakhali, Bangladesh