Frabex®

Tranexamic Acid BP

Composition
Frabex® 500 Tablet : Each tablet contains Tranexamic acid BP 500 mg.
Frabex® 500 Injection : Each ampoule contains Tranexamic Acid BP 500 mg.

Pharmacology
Tranexamic Acid has a strong inhibitory effect on the activation of plasminogen, i.e. the conversion of plasminogen to plasmin, in the fibrinolytic system. The half life is 1-2 hours. Plasma protein binding is 3% at therapeutic plasma levels. Tranexamic Acid is rapidly absorbed from the gastrointestinal tract. Maximum serum levels reached within 2-3 hours.

Indications
1. Haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis that may occur in conditions:

- Prostatectomy and bladder surgery
- Menorrhagia
- Epistaxis
- Conisation of the cervix
- Management of dental extraction in patients with coagulopathies
- 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 abruption of placenta and post-partum haemorrhage, in leukaemia and liver diseases and in connection with thrombolytic therapy with streptokinase.
3. Hereditary angioneurotic oedema.

Dosage and 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 1ml/minute, two to three times daily.
For the indications listed below the following doses are recommended.
Prostatectomy:
5-10 ml by slow intravenous injection every eight hours (the first injection being given during the operation) for the first three days after surgery; thereafter 1-1.5 gm tablets orally three to four times daily until macroscopic haematuria is no longer present.
Menorrhagia:
1-1.5 gm tablets orally three to four times daily for three to four days.
Epistaxis:
1.5 gm tablets orally 3-4 times daily for four to ten days. Tranexamic Acid may be applied topically to the nasal mucosa of patients suffering from epistaxis. This can be done by soaking a gauze strip in the solution, and then packing the nasal cavity.
Haematuria:
1-1.5 gm tablets orally 2-3 times daily until macroscopic haematuria is no longer present.
Conisation of the Cervix:
1-1.5 gm tablets orally 3 times a day for 12 to 14 days post-operatively.
Dental Surgery In Patients With Coagulopathy:
Immediately before surgery, 10 mg per kg body-weight should be given intravenously. After surgery, 25 mg per kg body-weight is given orally three to four times daily for six to eight days. Coagulation factor concentrate might be necessary to administrate.
General Fibrinolysis:
1.0 gm (10 ml) by slow intravenous injection three to four 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:
1-1.5 tablets gm orally two to three times daily as intermittent or continuous treatment depending on whether the patient has prodromal symptoms or not.
Renal Insufficiency:
For patients with impaired renal function, the following dosages are recommended:

Serum creatinine (micromol/L)	Dose IV (mg/kg)	Dose Orally (mg/kg)	Dose frequency (Per day)
120-249	10	15	twice
250-500	10	15	once
>500	5	7.5	once

Children:
Oral dose (Tablet): 25 mg/kg 2 to 3 times daily for 7 to 10 days.
Injection: 10 mg/kg at 6 to 8 hours interval for 7 to 10 days .

Contraindications
Active thromboembolic disease, such as deep vein thrombosis, pulmonary embolism and cerebral thrombosis, Subarachnoid haemorrhage.
Hypersensitivity to Tranexamic Acid or any of the ingredients

Warnings and Precautions
Patients with irregular menstrual bleeding, patients with a high risk of thrombosis (a previous thromboembolic event and a family history of thromboembolic disease) should use it only if there is a strong medical indication and under strict medical supervision. Patients with disseminated intravascular coagulation (DIC), who require treatment with it must be under the strict supervision of a physician experienced in treating this disorder.
In the long-term treatment of patients, regular eye examination should be performed. If a colour vision disorder occur during the course of treatment, the drug should be discontinued.

Pregnancy & Lactation
US FDA pregnancy category B.
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 foetal damage.

Tranexamic Acid is excreted into breast milk, but it is not likely to influence the child at therapeutic doses.

Adverse Effects
Dose-dependent gastrointestinal discomfort is the most commonly reported undesirable effect, but it is usually of mild and temporary in nature. Allergic skin reactions have been reported as an uncommon undesirable effect. Hypotension may occur after fast injection.

Drug Interactions
Clinically important interactions have not been observed with Tranexamic Acid.

Overdose
Symptoms: nausea, vomiting, dizziness, and headache.
Treatment of overdosage: If justified, initiate vomiting, then gastric lavage, charcoal therapy and symptomatic treatment. Maintain adequate diuresis.

Pharmaceutical Precautions
Tranexamic Acid injection should not be mixed with blood for transfusion or infusion solutions containing penicillin.

Storage
Keep protected from light and moisture. Store below 30^0 C.

How Supplied
Frabex® 500 Tablet: Box containing 20 tablets in blister pack.
Frabex® 500 Injection : Box containing 6 ampoules in blister pack

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH