

Fibrino®

Tranexamic Acid BP Film Coated Tablet and Injection

DESCRIPTION

Fibrino® is a preparation of Tranexamic Acid. It is an antifibrinolytic compound, which is a potent competitive inhibitor of the activation of plasminogen to plasmin. At much higher concentrations it is a non-competitive inhibitor of plasmin. The antifibrinolytic activity of Tranexamic Acid is approximately ten times greater than that of aminocaproic acid.

INDICATIONS

Fibrin dissolution can be impaired by the administration of **Fibrino®**, which inhibits fibrinolysis. **Fibrino®** is indicated in the treatment of:

- Prostatectomy and bladder surgery
- Dental extraction in patients with haemophilia
- Conisation of the cervix
- Traumatic hyphaema
- Management of menorrhagia
- Hereditary angioneurotic oedema
- Epistaxis &
- In thrombolytic overdose

DOSAGE AND ADMINISTRATION

Intravenous administration is necessary only if it is difficult to give adequate doses by mouth. The recommended standard dose is 2-3 tablets of 0.5 g two to three times daily. For the indications listed below the following doses are recommended.

Local fibrinolysis

The recommended standard dose is 2-3 tablets of 0.5 g daily three times daily. If treatment continues for more than three days, consideration should be given to the use of tablets. Alternatively, following an initial intravenous injection, subsequent treatment may proceed by intravenous infusion. Following addition to suitable diluents, **Fibrino®** may be administered at a rate of 25-50 mg/kg body wt/day.

Prostatectomy

After intravenous 1-1.5 g orally three to four times daily until macroscopic haematuria is no longer present.

Menorrhagia

1-1.5 g orally three to four times daily for three to four days. **Fibrino®** therapy is initiated when bleeding has become profuse.

Epistaxis

1.5 g orally three times daily for four to ten days. Tranexamic Acid solution for injection 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 g orally two to three times daily until macroscopic haematuria is no longer present.

Conisation of the Cervix

1.5 g orally three times a day for 12 to 14 days post-operatively.

Dental Surgery in Patients with Coagulopathies

Immediately before surgery, 10 mg per kg body-weight should be given intravenously. After surgery, 25 mg per kg body-weight are given orally three to four times daily for six to eight days. Coagulation factor concentrate might be necessary to administer.

Hereditary Angioneurotic Oedema

1-1.5 g orally two to three times daily as intermittent or continuous treatment depending on whether the patient has prodromal symptoms or not.

Children: According to body weight (10 mg/kg-body wt/ 2-3 times daily)

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

Real insufficiency

For patients with impaired renal function, the following dosages are recommended:

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

SIDE-EFFECTS

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

Frequency of undesirable effects at a dose of 4 g/day.

CONTRAINDICATIONS

Tranexamic Acid is contraindicated in severe renal failure because of risk of drug accumulation & active thromboembolic disease. Patients with Hematuria should not be used Tranexamic Acid.

OVERDOSAGE

There is no known case of overdose of **Fibrino®** tablet and injection. Symptoms may be nausea, vomiting, orthostatic symptoms and/or hypotension.

USE IN PREGNANCY AND LACTATION

Use in pregnancy

There are no adequate and well-controlled studies in pregnant women. Tranexamic acid crosses over the fetus. This drug should be used during pregnancy only if clearly needed.

Use in lactation

Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration serum level and the drug may be given during lactation without risk to the child.

PHARMACEUTICAL PRECAUTION

Store in a dry place, away from light. Keep out of reach of children.

PACKAGING

Fibrino® Tablet : Box containing 2 strips of 10 tablets each. Each film-coated tablet contains Tranexamic Acid BP 500 mg.

Fibrino® IV Injection : Box containing 1 strip of 5 ampoules each. Each ampoule contains Tranexamic Acid BP 100 mg/ml.

SK+F

Manufactured by

ESKAYEF BANGLADESH LIMITED

GAZIPUR, BANGLADESH

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PM01919 V01