Fibrino®

Tranexamic Acid BP Capsule 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 capsules of 0.5 g, 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:

Local fibrinolysis

The recommended standard dose is 2-3 capsules of 0.5 g daily three times daily. If treatment continues for more than three days, consideration should be given to the use of capsules. 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 administrate.

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 (μ mol/L)	I.V. Dosage	Capsules	Dose frequency
120 to 250 (1.36 to 2.83 mg/dL)	10 mg/kg	15 mg/kg	Twice daily
250 to 500 (2.83 to 5.66 mg/dL)	10 mg/kg	10 mg/kg	Daily
>500 (>5.66 mg/dL)	10 mg/kg every 41 hours or 5 mg/kg every 24 hours	5 mg/kg every 48 hours or 7.5 mg/kg every 24 hours	Daily

CONTRAINDICATIONS

❖ Acquired defective color vision
❖ Active intravascular clotting
❖ Subarachnoid hemorrhage

PRECAUTIONS

Concerns related to adverse effects:

❖ Thrombotic events: Venous and arterial thrombosis or thromboembolism, including central retinal artery/vein obstruction, has been reported. Use with caution in patients with thromboembolic disease.
❖ Ureteral obstruction: Use with caution in patients with upper urinary tract bleeding, ureteral obstruction due to clot formation has been reported.
❖ Visual abnormalities: Visual defects (eg, color vision change, visual loss) have been reported; in patients being treated for longer than several days, monitor ophthalmic examination at baseline and regular intervals during the course of therapy; discontinue treatment if changes in ophthalmic examination occur. Use is contraindicated in patients with acquired defective color vision since this would prohibit monitoring one endpoint as a measure of ophthalmic toxicity.

Disease-related concerns:

❖ Disseminated intravascular coagulation (DIC): Use with extreme caution in patients with DIC requiring antifibrinolytic therapy; patients should be under strict supervision of a physician experienced in treating this disorder.
❖ Renal impairment: Use with caution in patients with renal impairment; dosage modification may be required.
❖ Vascular disease: Use with caution in patients with uncorrected cardiovascular or cerebrovascular disease due to the complications of thrombosis.

Concurrent drug therapy issues:

❖ Anti-inhibitor coagulant complex/factor IX complex concentrates: Concurrent use is not recommended due to the increased risk of thrombosis.

ADVERSE REACTIONS

Cardiovascular: Hypotension (with rapid I.V. injection)
Endocrine & metabolic: Unusual menstrual discomfort
Gastrointestinal: Diarrhoea, nausea, vomiting
Ocular: Blurred vision

OVERDOSAGE

There is no known case of overdose of Tranexamic Acid. Symptoms may be nausea, vomiting, orthostatic symptoms and/or hypotension.

USE IN 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. Because animal reproduction studies are not always predictive of human response, 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.

PEDIATRIC USE

The drug has limited use in pediatric patients, principally in connection with tooth extraction. The limited data suggest that dosing instructions for adults can be used for pediatric patients needing Tranexamic Acid therapy.

PHARMACEUTICAL PRECAUTION

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

PACKAGING

Fibrino® Capsule : Box containing 3 strips of 6 capsules each. Each capsule contains Tranexamic Acid BP 500 mg.

Fibrino® Injection : Box containing 1 strip of 5 ampoules each. Each ampoule contains Tranexamic Acid BP 500 mg/5ml.

SK+F
Manufactured by
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