Anaxyl®

Tranexamic acid

Anaxyl ® is a preparation of Tranexamic acid which prevents haemorrhage or risk of haemorrhage in increased fibrinolysis or fibrinogenolysis. Tranexamic acid produces an antifibrinolytic effect by competitively inhibiting the activation of plasminogen to plasmin, thereby preventing the breakdown of fibrin clots and stabilization of fibrin structures.

Indications

Anaxyl® capsule and injection are indicated in –

1. Haemorrhage associated with excessive fibrinolysis. Local fibrinolysis may occur in the conditions e.g. prostatectomy and bladder surgery, menorrhagia, epistaxis, conisation of cervix, management of dental extraction in patients with coagulopathies, ulcerative colitis, haematuria and 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. In prophylaxis of hereditary angioneurotic oedema.

Dosage and administration

Adults:

The recommended standard dose is 2-3 capsules (1-1.5 g) or 5-10 ml (0.5-1 g) by slow intravenous infusion at a rate of 1 ml /min two to three times daily.

*Dosage of **Anaxyl®** according to indication-*

Prostatectomy: 5-10 ml (0.5-1 g) by slow intravenous infusion every 8 hours (the first injection being given during the operation) for the first 3 days after surgery. Thereafter 2-3 capsules (1-1.5 g) three to four times daily until macroscopic haematuria is no longer present.

Menorrhagia: Orally 2-3 capsules (1-1.5 g) three to four times daily for 3 to 4 days. **Anaxyl®** therapy is initiated when bleeding has become profuse.

Epistaxis: Orally 3 capsules (1.5 g) three times daily for 4 to 10 days. **Anaxyl®** 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: Orally 2-3 capsules (1-1.5 g) two to three times daily until macroscopic haematuria is no longer present.

Conisation of the cervix: Orally 3 capsules (1.5 g) three times a day for 12 to 14 days post-operatively.

Dental surgery in patients with coagulopathies: Immediately before surgery, 10mg /kg body-weight should be given intravenously. After surgery, 25mg /kg body-weight are given orally three to four times daily for 6 to 8 days. Coagulation factor concentrate might be necessary to administrate.

General fibrinolysis: 10 ml (1 g) 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: Orally 2-3 capsules (1-1.5 g) 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 dose of Tranexamic Acid should be decreased as there is a chance of accumulation.

For these patients the following dosages are recommended:

Serum creatinine concentration (µ mol/L)	**IV dose**	**Oral dose**	**Dose frequency**
120-249	10 mg/kg	15 mg/kg	Twice daily
250-500	10 mg/kg	15 mg/kg	Once daily
>500	5 mg/kg	7.5 mg/kg	Once daily
	10 mg/kg	15 mg/kg	Once every 48 hours

For intravenous infusion **Anaxyl®** injection may be mixed with most solutions for infusion such as electrolyte solutions, carbohydrate solutions, amino acid solutions and dextran solutions. The mixture should be prepared the same day the solution is to be used. Heparin may be added to **Anaxyl®** injection. **Anaxyl®** injection should not be mixed with blood. The drug is a synthetic amino acid and should not be mixed with solutions containing penicillin.

Children:
For the inhibition of fibrinolysis, hereditary angioedema
By mouth: Child 1 month to 18 years 15-25 mg/kg (max. 1.5 g) two to three times daily
By intravenous injection over at least 10 minutes: Child 1 month to 18 years 10 mg/kg (max. 1 g) two to three times daily
By continuous intravenous infusion: Child 1 month to 18 years 45 mg/kg over 24 hours.
For the prevention of excessive bleeding after dental procedures (e.g. in hemophilia)
Child 6-18 years 10 mg/kg (max. 1.5 g) by intravenous injection pre-operatively, followed by 15-25 mg/ kg (max. 1.5 g) two to three times daily by mouth for up to 8 days.
For menorrhagia
By mouth: Child 12-18 years the recommended dose is 1 g three to four times daily for up to 4 days; max. 4 g daily (initiate when menstruation has started).

Geriatric patients:
Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function. Because elderly patients are more likely to have decreased renal function it may be useful to monitor renal function.

Use in pregnancy and lactation
Tranexamic Acid is in pregnancy category B. As there are no adequate and well controlled studies in pregnant women, this drug should be used during pregnancy only if clearly needed. Tranexamic Acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood. Caution should be exercised when Tranexamic Acid is administered to a nursing woman.

Side effects
Tranexamic Acid appears to be well tolerated. The side effects are nausea, vomiting, diarrhoea (dose should be reduced); rarely disturbances in colour vision (treatment should be discontinued) and thromboembolic events, allergic skin reactions; giddiness and hypotension on rapid intravenous injection.

Contraindications
Tranexamic Acid should not be given in patients with a history or risk of thrombosis, unless at the same time it is possible to give treatment with anticoagulants. It is also contraindicated in patients with active thromboembolic disease such as deep vein thrombosis, pulmonary embolism and cerebral thrombosis and subarachnoid haemorrhage. Tranexamic Acid preparations should not be given to patients with acquired disturbances of color vision.

Precautions
Tranexamic Acid should be used with caution in patients with renal impairment. The dose should be reduced beacause of high risk of accumulation. Caution should also be exercised in case of massive haematuria (avoid if risk of ureteric obstruction), disseminated intravascular coagulation (patient must be under the supervision of a physician experienced in treating this disorder), irregular menstrual bleeding (cause should be established before initiating therapy). Drugs with actions on haemostasis should be given with caution to patients on antifibrinolytic therapy.

Warnings
For patients who are to be treated continually for longer than several days, an ophthalmological examination, including visual acuity, colour vision, eye-ground and visual fields, is advised, before commencing and at regular intervals during the course of treatment. Tranexamic Acid should be discontinued if the changes in examination results are found.

Drug interactions

Clinically important interactions have not been observed with Tranexamic Acid. Because of the absence of interaction studies, simultaneous treatment with anticoagulants must take place under the strict supervision of a physician experienced in this field.

Overdosage

Symptoms: nausea, vomiting, dizziness, and headache. Treatment of overdosage: if justified, vomiting should be initiated, then gastric lavage, charcoal therapy and symptomatic treatment. Adequate diuresis should be maintained. Toxicity: 37 g of Tranexamic acid caused mild intoxication in a seventeen-year-old patient after gastric lavage.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Presentation

Anaxyl® 500 capsule: Each capsule contains Tranexamic Acid BP 500 mg.
Anaxyl® 500 IV injection : Each 5 ml ampoule contains Tranexamic Acid BP 500 mg.

Package quantities

Anaxyl® 500 capsule : Carton of 20 capsules in blister.
Anaxyl® 500 IV injection : Carton of 5 ampoules.

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