# TranAcid

**Composition :**
**Each hard gelatin capsule contains :**
Tranexamic acid 250 mg

**Other ingredients :** Silica colloidal anhydrous (Aerosil 200), microcrystalline cellulose, Magnesium stearate pharmagrade, Gelatin capsule size "1"

**Pharmacodynamics :**
Tranexamic acid is a competitive inhibitor of plasminogen activation, and at much higher concentration, a non competitive inhibitor of plasmin. It forms a reversible complex that displaces plasminogen from fibrin resulting in inhibition of fibrinolysis. It also inhibits the proteolytic activity of plasmin.

**Pharmacokinetics :**
Tranexamic acid is absorbed from the gastrointestinal tract with peak plasma concentrations occurring after about 3 hours. Bioavailability is about 30 to 50 %. Tranexamic acid is widely distributed throughout the body and has very low protein binding. It diffuses across the placenta and is distributed into breast milk. Tranexamic acid has a plasma elimination half-life of about 2 hours. It is excreted in the urine mainly as unchanged drug.

**Indications :**
- Hemorrhage in patients with hemophilia
- Prevention of bleeding after surgery or trauma e.g., tonsillectomy and adenoidectomy, prostatic surgery.
- Menorrhagia

**Dosage and administration :**
Adults: Oral doses are 15-25 mg/Kg body weight 2-4 times daily. Should be taking 2-8 days following surgery. Alternatively, begin 1 day prior to surgery.
***Dosing adjustment/interval in renal impairment***
$Cl_{cr}$ 50-80 ml/minute: Administer 50% of normal dose or 15 mg/kg twice daily orally.
$Cl_{cr}$ 10-50 ml/minute: Administer 25% of normal dose or 15 mg/kg/day orally.
$Cl_{cr}$ < 10 ml/minute: Administer 10% of normal dose or 15 mg/kg/dose every 48 hours orally.

**Adverse Effects :**
Tranexamic acid appears to be well tolerated.
> 10% Gastrointestinal disturbances (Diarrhea, nausea, vomiting)
1-10% Hypotension, thrombosis, blurred vision
< 1% Unusual menstrual discomfort.

**Warning and Precautions :**
- Use with caution in patients with cardiovascular disease and cerebrovascular disease.
- In patients with renal impairment, use with caution and dosage modification required.
- When used for subarachnoid hemorrhage, ischemic complications may occur.
- Use with caution in patients with thromboembolic disease; may increase risk of thrombosis.
- Ophthalmic exam before and during therapy required if patient is treated beyond several days.

**Contraindications :**
Acquired defective color vision, subarachnoid hemorrhage, active intravascular clotting.

**Drug Interactions :**
Drug with actions on hemostasis should be given with caution to patients on antifibrinolytic therapy, Tranexamic acid. The potential for thrombus formation maybe increased by oestrogens, for example, or the action of Tranexamic acid antagonized by compounds such as thrombolytics.

**Pregnancy and Lactation :**
Pregnancy risk factor; B
Tranexamic acid is present in the mother's milk. Caution should be exercised when Tranexamic acid is administered to a nursing woman.

**Overdose and Treatment :**
Symptom of over dosage may be nausea, vomiting, orthostaticsymptoms or hypotension. There is no known antidote for Tranexamic acid acid overdose. In the event of overdose, the patients should be treated symptomatically and supportive measure should be instituted as required.

**Storage Condition :**
Store below 25°C in a dry place, away from direct sunlight.

**Shelf Life :**
Two years from manufacturing date.

**Product specification :** Manufacturer

**Packaging :** Polypropylene bottle containing 500 hard gelatin capsules each.

Manufacturer :
**MEGA LIFESCIENCES Public Company Limited**
384 Pattana 3 Rd. Bangpoo Industrial Estate,
Samutprakarn, Thailand.

**Date of revision of package insert :** 1 May 2015

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