HAEMIC®
(Tranexamic Acid)

250mg, 500mg
Capsules J.P.

500mg/5mL
I.M./I.V. Injection B.P.

1000mg/10mL
I.V. Injection B.P.

ہیمک
(ٹرانزامک ایسڈ)

۲۵۰ ملی گرام کیپسولز جے۔پی۔
۵۰۰ ملی گرام کیپسولز جے۔پی۔
۵۰۰ ملی گرام/۵ ملی لیٹر انجکشن بی۔پی۔
۱۰۰۰ ملی گرام/۱۰ ملی لیٹر انجکشن بی۔پی۔

عضلاتی/وریدی استعمال کے لئے
صرف وریدی استعمال کے لئے

QUALITATIVE AND QUANTITATIVE COMPOSITION

Haemic® Capsules J.P. 250mg
Each capsule contains: Tranexamic Acid B.P. 250mg,
Haemic® Capsules J.P. 500mg
Each capsule contains: Tranexamic Acid B.P. 500mg,
Haemic® Injection B.P. 500mg/5mL
Each 5mL contains: Tranexamic Acid B.P. 500mg,
Each mL contains: Tranexamic Acid B.P. 100mg
Haemic® Injection B.P. 1000mg/10mL
Each 10mL contains: Tranexamic Acid B.P. 1000mg
Each mL contains: Tranexamic Acid B.P. 100mg

CLINICAL PHARMACOLOGY

Mechanism of Action: Antiplasmin action: Tranexamic Acid binds strongly with the lysine binding site (LBS), the site of fibrin affinity of plasmin and plasminogen, and inhibits the binding of plasmin and plasminogen to fibrin. Therefore, the degradation of fibrin by plasmin is strongly inhibited. In the presence of antiplasmins, such as α 2-macro globulin, in the plasma, the antifibrinolytic action of Tranexamic Acid even further strengthened.
Hemostatic action: Abnormally exacerbated plasmin causes inhibition of platelet aggregation, decomposition of coagulation factors, etc., but even mild exacerbation causes characteristic fibrin degeneration to occur first. Therefore, in cases of ordinary hemorrhages. Tranexamic Acid appears to cause hemostasis by suppressing this fibrin degradation.
Antiallergic and anti-Inflammatory actions: Tranexamic Acid inhibits the production of kinin and other active peptides.
Pharmacodynamics: Tranexamic acid exerts an anti-haemorrhagic activity by inhibiting the fibrinolytic properties of plasmin. A complex involving tranexamic acid, plasminogen is constituted; the tranexamic acid being linked to plasminogen when transformed into plasmin.
Pharmacokinetics: Absorption and Distribution: Peak plasma concentrations of tranexamic acid are obtained rapidly after a short intravenous infusion after which plasma concentrations decline in a multi-exponential manner. The plasma protein binding of tranexamic acid is about 3% at therapeutic plasma levels and seems to be fully accounted for by its binding to plasminogen. Tranexamic acid does not bind to serum albumin. The initial volume of distribution is about 9 to 12 liters. Tranexamic acid passes through the placenta. Following administration of an intravenous injection of 10 mg/kg to 12 pregnant women, the concentration of tranexamic acid in serum ranged 10-53 µg/mL while that in cord blood ranged 4-31 µg/mL. Tranexamic acid diffuses rapidly into joint fluid and the synovial membrane. Following administration of an intravenous injection of 10 mg/kg to 17 patients undergoing knee surgery, concentrations in the joint fluids were similar to those seen in corresponding serum samples. The concentration of tranexamic acid in a number of other tissues is a fraction of that observed in the blood (breast milk, one hundredth; cerebrospinal fluid, one tenth; aqueous humor, one tenth). Tranexamic acid has been detected in semen where it inhibits fibrinolytic activity but does not influence sperm migration.
Metabolism and Excretion: It is excreted mainly in the urine as unchanged drug. Urinary excretion via glomerular filtration is the main route of elimination. Renal clearance is equal to plasma clearance (110 to 116 mL/min). Excretion of tranexamic acid is about 90% within the first 24 hours after intravenous administration of 10 mg/kg body weight. Elimination half-life of tranexamic acid is approximately 3 hours.

INDICATIONS AND USAGE

Hemorrhagic tendency considered to involve systemically exacerbated fibrinolysis (leukemia, hypoplastic anemia, purpura or abnormal hemorrhages during or after operation). Abnormal bleeding considered to involve locally exacerbated fibrinolysis (Pulmonary, nasal, genital, or renal hemorrhages or abnormal hemorrhages during or after prostate surgery). Symptoms such as erythema, swelling or itchiness in the following diseases: Eczema or similar diseases, urticarial, drug rash or toxic exanthema. Symptoms such as pharyngodynia, redness, hyperemia or swelling in the following diseases: Tonsillitis, pharyngo-laryngitis. Pain in the oral cavity or mucosal aphtha in cases of stomatitis. Tranexamic acid Injection is indicated in patients with haemophilia for short-term use (two to eight days) to reduce or prevent haemorrhage and reduce the need for replacement therapy during and following tooth extraction, menorrhagia and metrorrhagia, gynecological surgery or disorders of obstetric origin, thoracic and abdominal surgery and other major surgical intervention such as cardiovascular surgery.

CONTRAINDICATIONS

Tranexamic Acid is contraindicated: 1-In patients with acquired defective color vision, since this prohibits measuring one endpoint that should be followed as a measure of toxicity. 2-In patients with subarachnoid hemorrhage. Anecdotal experience indicates that cerebral edema and cerebral infarction may be caused by Tranexamic Acid in such patients. 3-In patients with active intravascular clotting.4-In patients with hypersensitivity to tranexamic acid or any of the ingredients, 5. History of convulsions, 6. Severe renal impairment (risk of accumulation).

INTERACTIONS

Drug with actions on hemostasis should be given with caution to patients on antifibrinolytic therapy. The potential for thrombus formation may be increased by estrogens, for example or the action of the antifibrinolytic antagonized by compounds such as thrombolytic.

USE IN SPECIFIC POPULATION

Pregnancy: Pregnancy Category B. There are no adequate and well controlled studies in pregnant women. However, tranexamic acid crosses the placenta and appears in cord blood. Use in pregnancy only if clearly needed.

Nursing Mothers: Tranexamic acid is present in the mother's milk at a concentration of about a hundredth of the corresponding serum levels. Caution should be exercised when Tranexamic Acid is administered to a nursing woman.

Pediatric Use: Tranexamic acid has had limited use in children, principally in tooth extraction. Limited data suggest that dosing instructions for adults can be used for children needing tranexamic acid therapy. **Geriatric Use:** 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, and of concomitant disease or other drug therapy.

PRECAUTIONS

For patients on prolonged treatment with tranexamic acid, perform an ophthalmological examination (including visual acuity, color vision, eyeground, and visual fields) before and at regular intervals during treatment.

Hepatic or renal impairment: Reduce dose in patients with renal insufficiency because of the risk of drug accumulation.

Hematuria: Ureteral obstruction due to clot formation in patients with upper urinary tract bleeding has been reported in patients treated with Tranexamic Acid.

Thromboembolic events: Patients with a high risk for thrombosis (a previous thromboembolic event and a family history of thromboembolic disease) should use tranexamic acid only if there is a strong medical indication and under strict medical supervision. Venous and arterial thrombosis or thromboembolism has been reported in patients treated with Tranexamic Acid. In addition, cases of central retinal artery and central retinal vein obstruction have been reported. Tranexamic acid should be administered with care in patients re-

ceiving oral contraceptives because of the increased risk of thrombosis.
Disseminated intravascular coagulation: Patients with disseminated intravascular coagulation (DIC) should in most cases not be treated with tranexamic acid. If tranexamic acid is given it must be restricted to those in whom there is predominant activation of the fibrinolytic system with acute severe bleeding. Consider an alternative treatment if menstrual bleeding is not adequately reduced by tranexamic acid. Indissoluble clots may develop in body cavities such as pleural space, joint spaces and urinary tract (e.g., renal pelvis, bladder) due to extravascular clots which may be resistant to physiologic fibrinolysis.

ADVERSE REACTIONS

Gastrointestinal disturbances (nausea, vomiting, diarrhea) may occur but disappear when the dosage is reduced. Allergic dermatitis, giddiness, and hypotension have been reported occasionally. Hypotension has been observed when intravenous injection is too rapid. To avoid this response, the solution should not be injected more rapidly than 1 mL per minute.

DOSAGE AND ADMINISTRATION

For adults: For Capsules: For adults 750 to 2000 mg/day of Tranexamic Acid is usually administered three to four times orally. The dosage should be adjusted according to the age of patients and severity of symptoms. **Local fibrinolysis:** 1–1.5 g (or 15–25 mg/kg) 2–3 times daily.
Menorrhagia (initiated when menstruation has started): 1g 3 times daily for up to 4 days; max. 4g daily Hereditary angioedema: 1–1.5 g 2–3 times daily **Epistaxis:** 1 g 3 times daily for 7 days. **For Intravenous Use:** By slow intravenous injection (rate not exceeding 100 mg/minute), local fibrinolysis, 0.5–1g 2–3 times daily
General fibrinolysis, 1g (or 15 mg/kg) every 6–8 hours.
By continuous intravenous infusion (Unlicensed route): Although it is not recommended for administration by infusion, but if needed to administer by continuous intravenous infusion then: for local fibrinolysis following initial treatment by intravenous injection, 25–50 mg/kg over 24 hours.
For Children: Inhibition of fibrinolysis, hereditary angioedema **By mouth (Child 1 month–18 years):** Same dosage as adults **By intravenous injection over at least 10 minutes (Child 1 month–18 years):** 10 mg/kg (max. 1 g) 2–3 times daily **By continuous intravenous infusion (Child 1 month–18 years):** 45 mg/kg over 24 hours Prevention of excessive bleeding after dental procedures (e.g. in haemophilia) **By intravenous injection pre-operatively (Child 6–18 years):** 10 mg/kg (max. 1.5 g) **By mouth pre-operatively (Child 6–18 years):**15–25 mg/kg (max. 1.5 g) **By mouth postoperatively (Child 6–18 years):** 15–25 mg/kg (max. 1.5 g) 2–3times daily for up to 8 days **Menorrhagia: By mouth (Child 12–18 years):** Same dosage as adults **For Special population:** For patients with moderate to severe impaired renal function, the following dosages are recommended:

Serum Creatinine (µmol/L)	**Tranexamic Acid I.V. Dosage**
120 to 250 (1.36 to 2.83 mg/dL)	10 mg/kg BID
250 to 500 (2.83 to 5.66 mg/dL)	10 mg/kg daily
>500 (>5.66 mg/dL)	10 mg/kg every 48 hours or 5mg/kg every 24 hours

For intravenous infusion, Tranexamic Acid Injection may be mixed with most solutions for infusion, such as electrolyte solutions, carbohydrate solutions, amino acid solutions, and Dextran solutions. Heparin may be added to Tranexamic Acid Injection. Tranexamic Acid Injection should NOT be mixed with blood. The drug is a synthetic amino acid, and should NOT be mixed with solutions containing penicillin.

OVERDOSAGE

There is no known case of overdosage of Tranexamic Acid. Symptoms of overdosage may be gastrointestinal, e.g., nausea, vomiting, diarrhoea; hypotensive, e.g., orthostatic symptoms; thromboembolic, e.g., arterial, venous, embolic, neurologic, e.g., visual impairment, convulsions, headache, mental status changes; myoclonus; and rash.

DOSAGE

As directed by the physician.

INSTRUCTIONS

Haemic Injection: Store below 30°C.
Protect from heat and light.
Any unused solution should be discarded.
Haemic Capsules: Store below 30°C. Protect from heat, light and moisture. Keep all medicines out of the reach of children.

PRESENTATION

Haemic® (Tranexamic Acid) Capsules J.P. 250mg are available in Alu/PVC blister pack of 10x10's.
Haemic® (Tranexamic Acid) Capsules J.P. 500mg are available in Alu/PVC blister pack of 2x10's.
Haemic® (Tranexamic Acid) Injection B.P. 500mg/5mL is available in ampoules pack of 2x5's.
Haemic® (Tranexamic Acid) Injection B.P. 1000mg/10mL is available in ampoules pack of 1x5's.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
ہیمک انجکشن: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔
گرمی اور روشنی سے محفوظ رکھیں۔
غیر استعمال شدہ سلوشن ضائع کر دیں۔
ہیمک کیپسولز: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔
گرمی، روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

For detailed information:

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