1. **Name of the Medicinal product:**

1.1 Product Name:

Hemsamic Capsule 500mg

1.2 Strength:
Each Capsule contains:
Tranexamic Acid….. 500mg
1.3 Pharmaceutical Dosage Form:
Capsule

2. **Qualitative and quantitative composition:**

Each Capsule contains:
Tranexamic Acid….. 500mg
For full list of excipients, see section 6.1 of SmPC

3. **Pharmaceutical form:**

Capsule

4. **Clinical particulars**

4.1 Therapeutic indications

- Bleeding tendency thought to be related to systemic hyperfibrinolysis (leukemia, aplastic anemia, purpura, etc., and abnormal bleeding during or after surgery) Abnormal bleeding thought to be related to local hyperfibrinolysis (pulmonary bleeding, nosebleeds, genital bleeding, renal bleeding, abnormal bleeding during or after prostate surgery).
- Symptoms such as erythema, swelling, and itching in the following diseases: eczema and similar diseases, urticaria, drug rash, and toxic rash Symptoms such as sore throat, redness, congestion, and swelling in the following diseases: tonsillitis, pharyngolaryngitis.
- Pain in the mouth and oral mucosa after stomatitis.

4.2 Posology and method of administration

Adults

The usual adult dose of tranexamic acid is 750-2,000 mg administered orally in 3-4 divided doses per day. The dosage may be increased or decreased depending on age and symptoms

Elderly:

Take care to lose weight, etc. Generally, physiological functions are often impaired.

4.3 Contraindications

Thrombin: The effect of promoting thrombus formation Yes, thrombus formation when used in combination the trend is increasing.

4.4 Special warnings and precautions for use:

- **Patients with complications or medical history**

  Patients with thrombosis (cerebral thrombosis, myocardial infarction, thrombophlebitis, etc.) and patients at risk of developing thrombosis.

- **Patients with consumption coagulopathy**

  Use in combination with heparin, etc. May stabilize blood clots.

- **Postoperative bedridden patients and patients undergoing pressure hemostasis**

This patient is prone to venous thrombosis, and administration of this drug may stabilize thrombi. Cases of pulmonary embolism occurring after ambulation or release of pressure have been reported.

4.5 Interaction with other medicinal products and other forms of interaction

- **Hemocoag Rase**: High-dose combination causes blood clots A tendency to form There is a risk of this happening. By Hemocoagulase The fibrin clot is formed The antiplasmin effect of this drug Therefore, it remains relatively long and There is risk of sustaining blockage
- **Batroxobin**: Causes thrombosis and embolism There is a risk of rubbing, produced by batroxobin DesA fibrin polymer Inhibits the degradation of mer.

4.6 Pregnancy and Lactation

Pregnancy

Administer only if the therapeutic benefits are judged to outweigh the risks.

Breastfeeding women:

Consider the therapeutic benefits and the benefits of breastfeeding and consider whether to continue or discontinue breastfeeding.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The following side effects may occur, so observe closely and if any abnormalities are found, discontinue administration or take other appropriate measures. Serious side effects include: Convulsions may occur in patients undergoing dialysis.
Hypersensitivity: Less than 0.1% Itching, rash, etc.
Digestive System: 0.1 to less than 1%. Loss of appetite, nausea, vomiting, Diarrhea, heartburn**.**

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

There is no information available for tranexamic acid capsule overdose.

5. Pharmacological Properties:

5.1 Pharmacological properties.

Pharmacotherapeutic group: Antifibrinolytics.
ATC code: B02AA02

Mechanism of action

Fibrinolysis (fibrinolysis) is involved in the breakdown of fibrin and the increased permeability of blood vessels under physiological and pathological conditions, and is related to the onset, progression, and healing of various bleeding symptoms and allergies, including biological reactions induced by plasmin.

Antiplasmin Action:

Tranexamic acid binds strongly to the lysine-binding site (LBS), which is the fibrin affinity site of plasmin and plasminogen, and prevents plasmin and plasminogen from binding to fibrin. This strongly inhibits fibrin degradation by plasmin.In the presence of plasma antiplasmin such as α-macroglobulin, the antifibrinolytic effect of tranexamic acid is further enhanced. 5)-9).

Hemostasis:

Abnormally elevated plasmin inhibits platelet aggregation and decomposes coagulation factors, but even mild elevation specifically triggers fibrin degradation. Therefore, in the case of general bleeding, tranexamic acid is thought to stop bleeding by inhibiting fibrin degradation.5).

Anti-allergic and anti-inflammatory effects:

Tranexamic acid inhibits the production of kinins and other active peptides by plasmin, which are responsible for increased vascular permeability and allergic and inflammatory lesions (guinea pigs and rats)

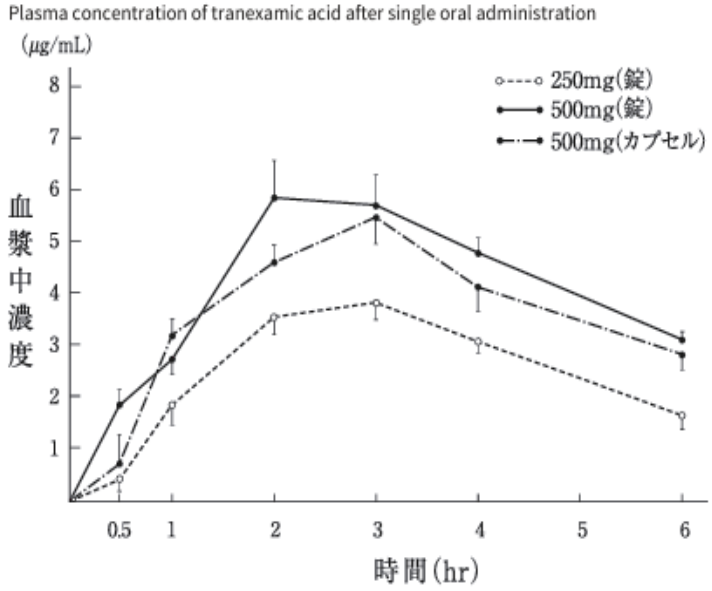
5.2 Pharmacokinetic Properties

Blood concentration

Single Dose:

When this drug was administered orally in a single dose to 15 healthy adult males, the plasma concentration profiles and pharmacokinetic parameters were as follows:

1) Plasma concentration of tranexamic acid after single oral administration.



Pharmacokinetic parameters of tranexamic acid after single oral administration

Dosage	Number of cases	Cmax (μg/mL)	Tmax (hr)	$t_{1/2}$ (hr)
250mg tablets	5	3.9	2-3	3.1
500mg tablets	5	6.0		3.3
500mg capsules	5	5.5		3.3

Distribution: To the mouse when C-tranexamic acid was administered orally at a single dose of 40 mg/kg, the maximum concentration was observed in most organs 1 to 2 hours after administration. The tissue distribution was highest in the liver, kidney, lung, and pancreas, followed by the uterus, spleen, heart, and muscle, and lowest in the brain.2).

Excretion: When tranexamic acid was administered orally at a single dose of 250 mg or 500 mg to 15 healthy adult males, approximately 40 to 70% of the administered dose was excreted unchanged in the urine within 24 hours after administration.

6. Pharmaceutical Particulars:

6.1 List of excipients
Empty hard gelatin Capsule# "1"

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years

6.4 Special precautions for storage
Protect from light and moisture store below 30°C.

6.5 Nature and contents of container
Alu-PVC blister pack of 2x10's & 3 x 10's Capsules, packed in unit carton along with a leaflet.

6.6 Special precautions for disposal and other handling
There are no special storage precautions. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder and manufacturing site addresses

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8. MARKETING AUTHORIZATION NUMBER: 017383-EX

9. DATE OF FIRST REGISTRATION: 24-01-2025

10. DATE OF REVISION OF THE TEXT: -