

120mm

170mm

Inxamic Injection / Capsule

(Tranexamic Acid)

انزیمیک
(ٹرانیکسامک ایسڈ)

COMPOSITION

INXAMIC 250mg Capsule

Each capsule contains:
Tranexamic acid250mg

(JP Specifications)

INXAMIC 500mg Capsule

Each capsule contains:
Tranexamic acid500mg

(JP Specifications)

INXAMIC 250mg Injection

Each 5ml ampoule contains:
Tranexamic acid250mg

(BP Specifications)

INXAMIC 500mg Injection

Each 5ml ampoule contains:
Tranexamic acid500mg

(BP Specifications)

DESCRIPTION:

Tranexamic acid (TXA) is used to treat or prevent excessive blood loss from trauma, surgery, and in various medical conditions including hemophilia and heavy menstrual bleeding. It comes in oral and intravenous form.

CLINICAL PHARMACOLOGY:

MECHANISM OF ACTION

Tranexamic acid is a synthetic analog of the amino acid lysine. It serves as an anti-fibrinolytic by reversibly binding four to five lysine receptor sites on plasminogen or plasmin. This prevents plasmin from binding to and degrading fibrin and preserves the framework of fibrin's matrix structure. Tranexamic acid has roughly eight times the anti-fibrinolytic activity of an older analogue, *ε-aminocaproic acid*.

• Anti-plasmin action:

INXAMIC 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 anti-plasmins, such as a2 - macro globulin, in the plasma, the anti-fibrinolytic action of INXAMIC is 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, INXAMIC appears to cause hemostasis by suppressing this fibrin degradation.

• Anti-allergic and anti-inflammatory actions:

INXAMIC inhibits the production of kinin and other active peptides etc. due to plasmin, which causes increase of vascular permeability, allergies and inflammatory lesions.

INDICATIONS:

• 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, urticaria, drug rash or toxic exanthema.

• Symptoms such as pharyngodynia, redness, hyperemia or swelling in the following diseases: Tonsillitis, pharyngolaryngitis.

• In the oral cavity or mucosal aphtha in cases of stomatitis.

DOSEAGE AND ADMINISTRATION:

• INXAMIC 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.

• INXAMIC injections:

Usual dose for adult is 250-500mg daily intravenously or intramuscularly divided 1-2 times a day. During or after operation, if necessary, 500-1000 g at a time is given intravenously or 500 2500 mg is given by intravenous drip infusion.

PHARMACOKINETICS:

• Blood concentrations:

The concentrations in the blood, when 250 mg and 500 mg of INXAMIC were administered orally to healthy adults, reached peak values 3.9 ug/ml (250 mg administration) and 6.0 ug/ml (500mg administration) 2,3 hours after administration.

The biological half-lives were 3.1 hours and 3.3 hours, respectively.

• Excretion:

When 500 mg of INXAMIC was administered orally to healthy adults the rate of excretion in the urine was about 30-52% by 24 hours after administration.

PRECAUTIONS FOR USE:

Following precautions should be observed.

• Patients with thrombosis (cerebral thrombosis, myocardial infarctions, thrombophlebitis, etc.) and Patients in whom thrombosis might occur.

• Patients with consumption coagulopathy (use concomitantly with heparin, etc.).

• Patients with a history of hypersensitivity to the drug.

ADVERSE DRUG REACTIONS:

• Hypersensitivity:

Stop administration when hypersensitive symptoms are observed.

• Digestive System:

Symptoms such as anorexia, nausea, vomiting, diarrhoea constipation, etc. may infrequently appear.

• Dermatological:

Symptoms such as itching, exanthema, etc. may appear rarely.

• Others:

Drowsiness may appear rarely.

SIDE EFFECTS:

The main side effects reported in 2,954 patients in clinical trial (including double blind trial) were anorexia in 0.61% (18 cases), nausea in 0.41% (12 cases), vomiting in 0.20% (6 cases), pyrosis in 0.17% (5 cases), itching in 0.07% (2 cases) and rash in 0.07% (2 cases).

DRUG INTERACTION:

Since there is a possibility of thrombus formation tendencies due to concomitant administration with large doses of hemostatic organ preparation or hemo-coagulase, be careful when administering concomitantly.

Others:

There have been reports of retinal changes when large doses were administered to dogs over long period.

OVERDOSE:

There is no known case of overdosage of INXAMIC Capsules and Injection. Symptoms of overdosage may be nausea, vomiting, orthostatic symptoms and/or hypotension.

CONTRAINDICATIONS:

INXAMIC Capsules and injection are contraindicated: In patients with acquired defective color vision, since this prohibits measuring one endpoint that should be followed as a measure of toxicity.

In patients with subarachnoid hemorrhage. Anecdotal experience indicates that cerebral edema and cerebral infarction may be caused by Tranexamic Acid in such patients.

In patients with active intravascular clotting.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight & moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

Single use only. Discard unused portion.

HOW SUPPLIED:

Inxamic 250mg Capsule

10 x 10's Capsules.

Inxamic 500mg Capsule

2 x 10's Capsules.

Inxamic 250mg Injection

5ml x 10's ampoules.

Inxamic 500mg Injection

5ml x 10's ampoules.

خوراک وطرریقہ استعمال:
ڈاکڑی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکڑ کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL PRIVATE LIMITED
Plot # 60, Sander Industrial Estate,
Lahore, Pakistan.

مخلول میں غیر مرل پڑے دردت نظر آئیں تو ایسی صورت میں
دوا استعمال نہ کریں۔