

PRESCRIBING INFORMATION

CLOTRAN

COMPOSITION

Each Tablet contains:

Tranexamic acid 500mg

DESCRIPTION

Tranexamic acid is an antifibrinolytic hemostatic agent used in severe hemorrhage.

PHARMACOLOGY

Pharmacodynamics

Tranexamic acid is a synthetic lysine amino acid derivative, which diminishes the dissolution of hemostatic fibrin by plasmin. In the presence of tranexamic acid, the lysine receptor binding sites of plasmin for fibrin are occupied, preventing binding to fibrin monomers, thus preserving and stabilizing fibrin's matrix structure.

Pharmacokinetics

Absorption: absorption of tranexamic acid after oral administration in humans represents approximately 30 to 50% of the ingested dose and bioavailability is not affected by food intake.

Volume of distribution: 9-12 L

Plasma protein binding: 3% bound to plasma proteins with no apparent binding to albumin.

Metabolism: only a small fraction of the drug is metabolized (less than 5%).

Elimination: It is eliminated by urinary excretion primarily via glomerular filtration with more than 90% of the dose excreted unchanged.

Clearance: 110 - 116 mL/min

INDICATIONS & DOSAGES

Menorrhagia & Metrorrhagia: 2 tablets t.i.d. as long as needed for upto 4 days.

Post-surgical Bleeding: 2 tablets t.i.d. daily as long as needed for upto 4 days.

Post-partum Haemorrhage: 2 tablets 3 to 4 times daily.

Post IUCD Bleeding: 2 tablets 3 to 4 times daily.

Placental Absorption: 2 tablets 3 to 4 times daily.

Conization of Cervix: 3 tablets t.i.d. for 7 days.

Epistaxis: 2 tablets t.i.d. for 7 days.

Dental Bleeding: 2-3 tablets every 8 hours.

Orthopaedic Surgery: 2 tablets t.i.d. for 7 days.

Urinary Tract Surgery: 2 tablets t.i.d. for 7 days.

SIDE EFFECTS

- Pale skin
- Trouble breathing with exertion
- Unusual bleeding or bruising
- Unusual tiredness/ weakness
- Abdominal or stomach pain
- Chills/fever
- Difficulty with moving
- Headache
- Joint/back pain muscle aching
- Cramping
- Stuffy / runny nose

CONTRAINDICATIONS

- Hypersensitivity to Tranexamic acid.
- Women who are using combination hormonal contraception.
- Women with active thromboembolic disease/ a history of intrinsic risk of thrombosis/ thromboembolism, including retinal vein or artery occlusion.

WARNINGS AND PRECAUTIONS

- Concomitant use of Tranexamic with Factor IX complex concentrates, anti-inhibitor coagulant concentrates or all-trans retinoic acid (oral tretinoin) may increase the risk of thrombosis.
- Visual or ocular adverse effects may occur.

- Cerebral edema and cerebral infarction may be caused in women with subarachnoid hemorrhage.
- Ligneous conjunctivitis has been reported in patients taking Tranexamic acid.

DRUG INTERACTIONS

Concomitant therapy with tissue plasminogen activators may decrease the efficacy of both Tranexamic and tissue plasminogen activators.

PREGNANCY AND LACTATION

Pregnancy category B

Tranexamic acid is present in the mother's milk at a concentration of about one hundredth of the corresponding serum concentration. Tranexamic should be used during lactation only if clearly needed.

PRESENTATION

Clotran is available in blister of 10 Tablets.

Each box contains 10X10's.

STORAGE

Store in a closed container at room temperature away from heat, moisture and direct light.

Keep out of the reach of children.

TARGETED DOCTORS

- Gynaecologist
- Surgeon
- Dentist
- GP
- Physician

COMPETITORS

| S.N. | BRAND NAME | MANUFACTURER | STRENGTH | MRP |
|-------------|-------------------|---------------------|-----------------|--------------|
| 1. | TRAMIC | QUEST | 500mg | Rs. 21.00 |
| 2. | TRANAREST | S.R. | 500mg | Rs. 2.25 |
| 3. | TRANCAP | TIME | 200/500mg | Rs. 12/24 |
| 4. | TRAX | ALIVE | 250/500mg | Rs. 12/25 |
| 5. | TRANEX | CUREX | 250/500mg | Rs. 9.5/18.5 |
| 6. | FIBRINIC | DJPL(NIROG) | 250/500/1000mg | Rs.11/20/39 |
| 7. | TRACID | LOMUS | 250/500mg | Rs. 12/24 |
| 8. | TAFCO | NATIONAL(STATUS) | 500mg | Rs. 22.00 |
| 9. | NEXTRA | SUMY | 250/500mg caps | Rs. 12/18 |
| 10. | XAMIC | TORRENT | 500mg | Rs. 275 |