

PRESCRIBING INFORMATION

CLOTRAN 250

COMPOSITION

Each Capsule contains:

Tranexamic acid 250mg

DESCRIPTION

Tranexamic acid is antifibrinolytic agent that can be used off- label for the treatment of melasma.

PHARMACOLOGY

Pharmacokinetics

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

Distribution: Volume of distribution is 9 to 12 L & protein binding is 3% at therapeutic plasma levels.

Metabolism: Only a small fraction of the drug is metabolized (less than 5%). Half life is 3 hours.

Route of elimination: urinary excretion is the main route of elimination via glomerular filtration with Clearance of about 110 - 116 mL/min.

PHARMACODYNAMICS

UV radiation induces synthesis of plasminogen activator by keratinocytes which results in increased conversion of plasminogen to plasmin. Plasminogen activator induces tyrosinase activity resulting in increases melanin synthesis. Whereas plasmin results in increased production of both arachidonic acid & fibroblast growth factor stimulates melanogenesis & neovascularisation. Tranexamic acid exerts effect on pigmentation by inhibiting UV induced plasminogen activator & plasmin activity.

INDICATIONS

Melasma, hyperpigmentation & skin whitening.

DOSAGES

The recommended dose is 250mg Caps b.i.d. for at least 4 to 8 weeks.

SIDE EFFECTS

Pale skin, trouble breathing with exertion & arterial and venous thromboses.

CONTRAINDICATIONS

Contraindicated in patients with known hypersensitivity, renal dysfunction, malignancy, cardiovascular, respiratory disease, current anticoagulant therapy & history of thromboembolic disease including DVT, PE, arterial thrombosis, stroke and subarachnoid hemorrhage.

WARNINGS & PRECAUTIONS

Before taking Tranexamic acid, tell your doctor or pharmacist if you are allergic to it or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

DRUG INTERACTIONS

Acetylsalicylic Acid, duloxetine, ibuprofen amoxicillin, diphenhydramine, pregabalin, mefenamic acid, metoprolol Tartrate, naproxen & paracetamol.

PREGNANCY AND LACTATION

Pregnancy category B

Tranexamic acid is excreted into human milk at a concentration of about one hundredth of the corresponding serum concentrations.

PRESENTATION

Tranexamic acid is available in alu-alu blister of 10 capsules.

Each box contains 10x10's.

STORAGE

Store at room temperature protected from light & moisture.

Keep out of the reach of children.