Grafiche Lama industrial printing	Specifiche cliente: **BIOINDUSTRIA L.I.M.** Oggetto: foglio illustrativo - Nome: **Acido tranexamico per Malesia** Codice: **M2K179/1** Dimensioni: **13x17 cm** Stampa: **F/R piegato**	Visto si stampi
Carattere usato: **NOME PRODOTTO:** Helv. neue bold corpo 12 Ridim. 95% **SOTTOTITOLO:** Helv. neue bold corpo 9 **TESTO:** Helv neue 7,5 rid 91%	**3a**	**Data:**

Nero			TIPO	Carta	GR/MG
/				USO MANO	60

TRANEXAMIC ACID 500mg/5mL INJECTION BIOINDUSTRIA L.I.M.

Tranexamic Acid 10% w/v

Presentation:
Tranexamic Acid 500mg/5 mL Injection Bioindustria Laboratorio Italiano Medicinali (L.I.M.): Each neutral glass ampoule contains sterile, clear, colourless, or slightly yellowish particle-free solution for IV injection. Each carton box contains five 5mL ampoules and one leaflet.

Composition:
Each ampoule of 5mL contains a solution of Tranexamic Acid at 10% w/v (500mg) in Water for Injection.

Pharmacodynamic:
Tranexamic acid is an antifibrinolytic agent, which competitively inhibits the activation of plasminogen to plasmin.

Pharmacokinetics:
Approximately 90% of an intravenously administered tranexamic acid dose is excreted, largely unchanged, in the urine within 24 hours. The plasma half-life is approximately 2 hours.

Indications:
Bleeding tendencies in which systemic hyperfibrinolysis is considered to be involved (leukemia, aplastic anemia, purpura and abnormal bleeding during or after operation).

Abnormal bleeding in which local hyperfibrinolysis is considered to be involved (pulmonary, nasal, vaginal or renal hemorrhage, abnormal bleeding during or after prostate surgery).

Symptoms e.g. erythema, swelling or pruritus in the following diseases:
Eczema or similar diseases, urticaria, drug eruptions or toxicoderma.

Symptoms e.g. pharyngalgia, redness, hyperemia or swelling in the following diseases:
Tonsillitis, pharyngolaryngitis.

Pain in the oral cavity or mucosal aphtha in cases of stomatitis.

Dosage and Administration:
Adults:
250 – 500mg (2.5 – 5 mL)/day by slow IV (1mL/min) in 1 - 2 divided doses.

500 - 1000 mg (5 – 10 mL) each time by slow IV (1mL/min) or 500-2500 mg (5 – 25 mL) by IV drip infusion as required during or after surgery.

Elderly: Since the elderly often have reduced physiological function, careful supervision and measures e.g. reducing the dose are recommended.

Instructions for Use/ Handling:
IV: With regard to IV administration, inject Tranexamic Acid Injection slowly (1mL/min). Symptoms e.g. nausea, chest discomfort, palpitations and a fall in blood pressure may rarely occur.

1. Inject Tranexamic Acid Injection carefully to avoid contact with nerves.

2. If repeated injection is required, change the injection site (e.g. alternate between the right and left arms). Special care should be observed when the drug is administered to premature infants, newborns, suckling infants and children.

3. If insertion of the injection needle induces intense pain or if blood flows back into the syringe, withdraw the needle immediately and perform injection at a different site.

Precautions When Opening the Ampoule:
To avoid contamination with foreign matter, wipe them off with an alcohol swab before opening the ampoule.

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Contraindications:
Patients with a history of hypersensitivity to tranexamic acid.

Tranexamic acid is contra-indicated in patients with a history of thromboembolic disease.

Special Warnings and Precautions:
Careful Administration:
Patients with thrombosis (cerebral thrombosis, myocardial infarction, thrombophlebitis) and patients at risk of thrombosis.

Tranexamic acid may stabilize thrombosis.

Patients with consumption coagulopathy (use concomitantly with heparin). It may stabilize thrombus.

Others:
Retinal degeneration has been reported with tranexamic acid in dogs after long-term, high dose administration.

Pregnancy and Lactation:
Pregnancy
Although there is no evidence from animal studies of a teratogenic effect, the usual caution with the use of drugs in pregnancy should be observed.

Lactation
Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood. An antifibrinolytic effect in the infant is unlikely.

Drug Interactions:
The solution for injection may be mixed with the following solutions:
Isotonic Sodium Chloride; Isotonic Glucose; 20% Fructose; 10% Invertose; Dextran 40; Dextran 70; Ringer's Solution.

Tranexamic Acid Solution for Injection may be mixed with heparin.

Incompatibilities:
Tranexamic Acid Solution for Injection should not be added to blood for transfusion, or to injections containing penicillin.

Adverse Reactions:
Gastro-intestinal disorders (nausea, vomiting, diarrhoea) may occur but disappear when the dosage is reduced. Rapid intravenous injection may cause dizziness and/or hypotension. Rare cases of thromboembolic events have been reported.

Nervous System Disorders:
Dizziness, convulsions.

Overdosage:
No cases of overdosage have been reported. Symptoms may be nausea, vomiting, orthostatic symptoms and/or hypotension. Maintain a high fluid intake to promote renal excretion.

Storage Conditions:
Store at room temperature below 30°C.
Discard any unused portion after opening.

Date of Revision of Package Insert:
08/02/2017

Manufactured by:
Bioindustria Laboratorio Italiano Medicinali S.p.A., Via De Ambrosiis 2, 15067 Novi Ligure (AL), Italy.

BIOINDUSTRIA LABORATORIO ITALIANO MEDICINALI S.p.A.

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