TRANEXAMIC ACID IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Tranexamic Acid Injection is contraindicated:

1. In patients with acquired defective color vision, since this prohibits measuring one endpoint that should be followed as a measure of toxicity (see WARNINGS).

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

3. In patients with active intravascular clotting.

4. In patients with hypersensitivity to tranexamic acid or any of the ingredients

WARNINGS

- Focal areas of retinal degeneration have developed in cats, dogs and rats following oral or intravenous tranexamic acid at doses between 250 to 1600 mg/kg/day (6 to 40 times the recommended usual human dose) from 6 days to 1 year. The incidence of such lesions has varied from 25% to 100% of animals treated and was dose-related. At lower doses some lesions have appeared to be reversible.

- Limited data in cats and rabbits showed retinal changes in some animals with doses as low as 126 mg/kg/day (only about 3 times the recommended human dose) administered for several days to two weeks.

- No retinal changes have been reported or noted in eye examinations in patients treated with tranexamic acid for weeks to months in clinical trials.

- However, visual abnormalities, often poorly characterized, represent the most frequently reported postmarketing adverse reaction in Sweden. For patients who are to be treated continually for longer than several days, an ophthalmological examination, including visual acuity, color vision, eye-ground and visual fields, is advised, before commencing and at regular intervals during the course of treatment. Tranexamic acid should be discontinued if changes in examination results are found.

- Convulsions have been reported in association with tranexamic acid treatment.

To report SUSPECTED ADVERSE REACTIONS, contact Acella Pharmaceuticals at 1-800-541-4802 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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