

10871-TRANEXAMIC ACID**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Tranexamic acid

Bulk code: 10871

1.2. Synonyms.

AMCA; Kyselina tranexamová; Trans-AMCA; CL-65336.

2. DESCRIPTION.

Appearance: Crystalline powder

Colour: White

Smell: Odourless

3. COMPOSITION/INFORMATION ON COMPONENTS.Formula: $C_8H_{15}NO_2$

CAS: 1197-18-8

EC: 214-818-2

Molecular weight: 157.2 g/mol

Chemical name: 4-(Aminomethyl)-cyclohexanecarboxylic acid

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Freely soluble in water and in glacial acetic acid. Practically insoluble in acetone and ethanol (96%)**5. PROPERTIES/USES**

ACTIVE PHARMACEUTICAL INGREDIENT.

Tranexamic acid is an antifibrinolytic drug that inhibits the breakdown of fibrin clots. It acts primarily by blocking the binding of plasminogen and plasmin to fibrin; direct plasmin inhibition occurs only to a limited extent. Tranexamic acid is used in the treatment and prophylaxis of bleeding associated with excessive fibrinolysis. It is also used in the prophylaxis of hereditary angioedema.

Studies have shown the efficacy of tranexamic acid as a depigmenting agent for melasma at concentrations of between 3% and 5%. Other bibliographical references show that liposomal tranexamic acid has a superior depigmenting effect than a topical application.

Tranexamic acid is also used in the treatment of hamartomas such as nevus flammeus (port wine stain) and nevus flammeus neonatorum.

10871-TRANEXAMIC ACID**6. DOSAGE.**

Tranexamic acid is administered orally for short-term use in localised bleeding (see more details in the literature); common oral doses are 1 to 1.5 g (or 15 to 25 mg/kg) 2 or 3 times daily.

When used in menorrhagia (see more details in the bibliography), a maximum dose of 4 g daily is administered orally for up to 5 days during menstruation.

Tranexamic acid is used for prolonged periods in hereditary angioedema (see more details in the bibliography) in doses of 1 to 1.5 g administered orally 2 or 3 times a day. It can be taken intermittently or continuously, and the dose can be reduced to 500 mg once or twice daily as attacks subside.

When used for short-term prophylaxis to prevent seizures related to surgery or dental work, a dose of 1 g 4 times daily can be given for 48 hours before and after the procedure.

For doses used with children, see further details in the bibliography.

Tranexamic acid solutions have been applied topically, e.g. as bladder irrigation or mouthwash.

7. REMARKS.

Storage: Store at room temperature ($25\pm 2^{\circ}\text{C}$) in a cool, dry place, away from light, in full, closed containers, in ventilated areas.

On the certificate of analysis for each batch you can check whether the batch is suitable for parenteral use or not.

8. BIBLIOGRAPHY.

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