

DICYNONE AMPOULES

Antihemorrhagic

Composition

DICYNONE

Each 2 ml ampoule contains: diethylammonium 1,4 dihydroxybenzenesulfonate (INN, etamsylate) 250 mg, antiox. (E 223) 0.8 mg.

Each tablet contains: diethylammonium 1,4 dihydroxybenzenesulfonate (INN, etamsylate) 250 mg.

DICYNONE 500

Each tablet contains: diethylammonium 1,4 dihydroxybenzenesulfonate (INN, etamsylate) 500 mg, antiox. (E 221).

Properties / Mode of action

Etamsylate is a synthetic antihemorrhagic and angioprotective drug acting on the first step of hemostasis (endothelium - platelet interaction). By improving platelet adhesiveness and restoring capillary resistance, it reduces the bleeding time and blood losses. Etamsylate has no vasoconstrictor action, it does not influence fibrinolysis nor modify the plasma coagulation factors.

Pharmacokinetics

After i.v. administration of 500 mg etamsylate, the maximum plasma level, i.e. 50 µg/ml, is reached at 10 minutes. The plasma half-life is around 1,9 h. About 85% of the administered dose are excreted in the first 24 h -urine.

When given p.o., etamsylate is resorbed through the gastrointestinal tract. After oral administration of 500 mg etamsylate, maximum plasma level, i.e. 15 µg/ml, is reached at 4 h. The plasma half-life is around 3,7 h. About 72% of the administered dose are excreted in the first 24 h-urine; the molecule is excreted unchanged.

Etamsylate crosses the placental barrier. Maternal and cord blood contains similar concentrations of etamsylate.

Indications

In surgery: Prevention and treatment of per- or postsurgical oozing in all delicate operations and in those affecting highly vascularized tissues: E.N.T., gynecology, obstetrics, urology, odontostomatology, ophthalmology, plastic and reconstructive surgery.

In internal medicine: Prevention and treatment of capillary hemorrhages of whatever origin or localization; hematuria, hematemesis, melena, metrorrhagia, primary or IUD-related menorrhagia, epistaxis, gingivorrhagia.

In pediatrics: Prevention of periventricular hemorrhages in premature babies.

Dosage

DICYNONE

Adults:

Presurgical: 1-2 ampoules i.v. or i.m. 1 hour before surgery.

Postsurgical: 1-2 ampoules i.v. Repeat the dosage if necessary.

Emergency cases, according to the severity of the case: 1-2 ampoules i.v. or i.m. Repeat every 4-6 hours as long as the risk of bleeding persists.

Local treatment: soak a swab with the content of an ampoule and apply to hemorrhagic area, or in the tooth socket after dental extraction. The application may be repeated when necessary; it may be associated with oral or parenteral administration.

Children: half the adult dose.

Pediatrics: 10 mg per kg body weight (0.1 ml=12.5 mg) injected intramuscularly within 2 hours after birth then every 6 hours for 4 days.

DICYNONE 500

Adults:

Postsurgical: 1 tablet, repeat every 4-6 hours as long as the bleeding risk persists.

Internal medicine: generally, 2-3 tablets daily; the duration of treatment depends on the results.

Gynecology, in meno-metrorrhagia: from the fifth day before the expected onset of the menstrual period 3 tablets daily for 10 days.

Children: half the adult dose.

Limitations for use - As for most drugs, Dicynone/Dicynone 500 should not be taken during the first trimester of pregnancy.

Adverse effects - Etamsylate does not induce serological or allergic side-effects.

Interactions - Dicynone/Dicynone 500 may be given in association with any other drug (for example anti-coagulants). When a perfusion with dextran is necessary, Dicynone has to be administered first.

Stability - Protect the ampoules from light. Discard Dicynone ampoules if the solution is coloured.

Dicynone/Dicynone 500 may be administered until the expiration date indicated on the package (EXP).

Presentations

DICYNONE

Ampoules (250 mg/2 ml): 3, 100