DICYNONE® 500 TABLETS

Antihemorrhagic

Composition

Active principle: etamsylate

Etamsylate 500 mg. Antiox. (E 221), excipients q.s. 1 tablet.

Properties / Effects

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

When given p.o., etamsylate is slowly absorbed from the gastrointestinal tract. After oral administration of 500 mg etamsylate maximum plasma level, i.e. 15 µg/ml, is reached at 4 h, but bioavailability is not known. The binding rate to plasma proteins is about 95 %. Plasma half-life is about 3.7 h. About 72 % of the administered dose is excreted in the first 24 h in urine, the molecule is excreted unchanged.

Etamsylate crosses the placental barrier. Maternal and cord blood contains similar concentrations of etamsylate. It is not known if etamsylate is excreted in the maternal milk.

Kinetics in particular situations

It is not known if the pharmacokinetic properties of etamsylate are modified in patients suffering from renal and/or hepatic function disorders.

Indications and usage

In surgery:

Prevention and treatment of pre- or postsurgical capillary hemorrhages in all delicate operations and in those affecting highly vascularised 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, epistaxis, gingivorrhagia.

In gynecology:

Metrorrhagia, primary or IUD-related menorrhagia in the absence of organic pathology.

Dosage

Adults:

Pre-surgical: 1 tablet (500 mg) 1 hour before surgery

Post-surgical: 1 tablet (500 mg) every 4 - 6 hours as long as the risk of bleeding persists.

Internal medicine: Generally 1 tablet 2 - 3 times a day (1000 - 1500 mg) to be taken with meals with a little water; treatment duration depends on the results obtained.

Gynecology, meno-metrorrhagia: 1 tablet 3 times a day (1500 mg) to be taken with meals with a little water. Treatment lasts 10 days and starts 5 days before the expected onset of menses.

Children: Because of its high concentration of active principle, Dicynone 500 is not appropriate for children.

Limitations for use

Contraindications

Acute porphyria.

Precautions

Parenteral administration of Dicynone may induce a drop in blood pressure, but no data has been reported on such a risk during oral administration.

If Dicynone 500 is administered for a reduction of excessive and/or prolonged menstrual hemorrhages, and no improvement is observed, possible pathological causes should be looked for and excluded.

Pregnancy / Breast-feeding

Pregnancy category C: studies in pregnant women or animals are not available.

As a precaution, Dicynone 500 should not be administered during the first trimester of pregnancy, whereas during the second and third trimesters, it should be adminstered only if the expected therapeutic benefit is judged as superior to the potential risk for the foetus.

In the absence of data regarding passage into maternal milk, lactations during treatment is not advisable or, if lactation is to be continued, the treatment must be stopped.

Adverse reactions

Rare: Gastralgia, nausea, headache, skin rash. In most cases, these symptoms disappear spontaneously. If they persist, the dosage should be reduced or the treatment withdrawn.

Interactions

No interaction is known up till now.

Overdosage

Signs of overdosage are unknown. In case of overdosage, symptomatic treatment should be initiated.

Particular remarks

Storage:

Dicynone 500 should not be administered after the expiration date indicated on the package.

Presentations

Tablets: Two strips each contain 7 tablets.

OM Laboratoires OM s.a., Meyrin - Geneve (Suisse)