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DICYNONE 250 Injection solution

OM Pharma

1. Name of the medicinal product

DICYNONE 250 Injection solution

2. Qualitative and quantitative composition

1 ampoule for injection contains:

Etamsylate 250 mg.

For excipients, see section 6.1.

3. Pharmaceutical form

Solution for injection.

4. Clinical particulars

4.1. Therapeutic indications

In surgery:

Prevention and treatment of pre-, per-, or postsurgical capillary haemorrhages in all delicate operations and in those affecting highly vascularised tissues: E.N.T., gynaecology, obstetrics, urology, odontostomatology, ophthalmology, plastic and reconstructive surgery.

In paediatrics:

Prevention of periventricular haemorrhages in premature babies.

4.2. Posology and method of administration

Adults

Presurgical: 1-2 ampoules i.v. or i.m. (250-500 mg) 1 hour before surgery.

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

Postsurgical: 1-2 ampoules (250-500 mg) every 4-6 hours as long as the risk of bleeding persists.

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

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

Children

Half the adult dose.

Neonatology: 10 mg per kg body weight (0,1 ml=12,5 mg) injected intramuscularly within 2 hours of birth then every 6 hours for 4 days.

4.3. Contra-indications

Acute porphyria.

Bronchial asthma, proven hypersensitivity to sulphites.

Hypersensitivity to the active substance or to any of the excipients.

4.4. Special warnings and special precautions for use

As parenteral administration of Dicynone 250 for injection may induce a drop in blood pressure, it is advised to carefully monitor patients suffering from blood pressure instability or hypotension (see "Adverse reactions").

4.5. Interactions with other medicinal products and other forms of interaction

Thiamine (vitamin B1) is inactivated by the sulphite contained in Dicynone 250 for injection.

If a perfusion with Dextran is necessary, Dicynone 250 must be injected first.

4.6. Pregnancy and lactation

Pregnancy category C: For etamsylate, no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see 5.3.). As a precaution, Dicynone should not be administered during the first trimester of pregnancy, whereas during the second and third trimester, it should be administered 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, lactation during treatment is not

advisable or, if lactation is to continue, the treatment must be stopped.

4.7. Effects on ability to drive and use machines
Dicynone 250 for injection has no effect on the ability to drive and use machines.

4.8. Undesirable effects
In certain cases, parenteral administration can produce a drop in blood pressure. Pressure returns to normal values within the next hours.

Rare: gastralgia, nausea, headache, skin rash.

In most cases these symptoms disappear spontaneously.

Dicynone 250 ampoules for injection contains sodium bisulphite as antioxidant that may cause allergic reactions, nausea and diarrhoea in susceptible patients. The allergic reactions may lead to anaphylactic shock and cause life-threatening asthma attacks. The incidence in the population is not known but is probably low. However, hypersensitivity towards sulphite is observed more frequently in asthmatics than in non-asthmatics (see "Contraindications" and "Precautions"). In case of hypersensitivity reactions, the administration of Dicynone 250 ampoules must be immediately stopped.

4.9. Overdose
No case of overdose has been reported. In case of overdosage, a symptomatic treatment should be initiated.

5. Pharmacological properties

5.1. Pharmacodynamic properties
ATC code: B02BX01 (Other systemic hemostatics)

Etamsylate is a synthetic antihaemorrhagic and angioprotective drug acting on the first step of haemostasis (endothelium-platelet interaction). By improving platelet adhesiveness and restoring capillary resistance, it is able to reduce bleeding time and blood losses.

Etamsylate has no vasoconstrictor action, it does not influence fibrinolysis nor modify the plasma coagulation factors.

5.2. Pharmacokinetic properties
After i.v. administration of 500 mg etamsylate, the maximum plasma level, i.e. 50 µg/ml, is reached after 10 minutes; plasma half-life is about 1,9h. About 85% of the administered dose are excreted in the first 24h-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.

5.3. Preclinical safety data
Acute and chronic toxicity studies, foetotoxicity and mutagenicity studies on etamsylate have not revealed any toxic effect.

6. Pharmaceutical particulars

6.1. List of excipients
1 ampoule contains:
- Sodium bisulfite
- Water for injection
- Antioxidant (E 223)
- Sodium hydrogen carbonate
- Nitrogen

6.2. Incompatibilities
Thiamine (vitamin B1) is inactivated by the sulphite contained in Dicynone 250 for injection.

If a perfusion with Dextran is necessary, Dicynone 250 must be injected first.

6.3. Shelf-life
Dicynone 250 ampoules should not be administered after the expiration date indicated on the package (EXP).

6.4. Special precautions for storage
Protect the ampoules from light. Discard Dicynone 250 ampoules if the solution is coloured. To be stored protected from heat (below 30°C).

Store in the original package.

6.5. Nature and content of container
2-ml neutral glass ampoules.

6.6. Instructions for use and handling
No special instructions.

7. Marketing authorization holder
OM PHARMA, 22, rue du Bois-du-Lan, 1217 Meyrin 2/Geneva, Switzerland