

DICYNONE® 250 mg/ 2 ml
Solution for injection

COMPOSITION

Active substance: Etamsylate

Excipients: sodium metabisulfite, sodium hydrogen carbonate, water for injections

PHARMACEUTICAL FORM AND QUANTITY OF ACTIVE SUBSTANCE PER UNIT

Solution for injection in an ampoule (2 ml).

Each ampoule contains 250 mg of etamsylate.

INDICATIONS

In general medicine:

- blood loss through fragile capillaries
- menorrhagia (heavy periods) with no detectable organic cause
- in general or specialized surgery (ENT, ophthalmology, gynaecology): reduction of blood loss during operations, particularly diffuse haemorrhage, patients treated with anticoagulants.

DOSAGE AND ADMINISTRATION

Usual dosages:

-Adults:

- emergency, 2 to 3 ampoules 3 times daily
- pre-operative period, 1 hour before surgery: 2 ampoules
- peri-operative period :according to requirement
- post-operative period: 1 ampoule, twice daily

-In newborn and children: half the adult dose

IV or IM ROUTE. The Injectable solution may also be used by the oral route (diluted in a half-glass water) or locally (dabbing).

CONTRAINDICATIONS

- Acute porphyria
- Bronchial asthma, confirmed hypersensitivity to sulphites
- Hypersensitivity to any of the ingredients of the medicinal product

SPECIAL WARNINGS AND PRECAUTIONS

Due to the risk of a fall in blood pressure during parenteral administration, caution is required in patients presenting unstable blood pressure or hypotension (see “Undesirable effects”).

DICYNONE 250 solution for injection contains sodium metabisulfite as antioxidant, which may cause allergic reactions, nausea and diarrhea in susceptible patients. The allergic reactions may go as far as anaphylactic shock and cause life-threatening asthma attacks. The prevalence in the population is not known but is probably low. However, hypersensitivity to sulphites is observed more frequently in patient with asthma than in those without asthma (see «Contraindications»). If a hypersensitivity reaction occurs, the administration of Dicynone 250 solution for injection must be stopped immediately.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

INTERACTIONS

INCOMPATIBILITIES

Thiamine (vitamin B1) is inactivated by the sulphite contained in DICYNONE 250 solution for injection. If a dextran infusion is required, DICYNONE 250 must be injected first.

PREGNANCY AND LACTATION

There are no clinical data available concerning use in pregnant women.

Caution is required if used during pregnancy.

In the absence of data concerning passage into breast milk, breast-feeding is inadvisable during treatment. Alternatively, the treatment should be stopped if breast-feeding is continued.

UNDESIRABLE EFFECTS

The side effects are classified according to the MedDRA convention by system organ class and by frequency as follows:

Very common ($\geq 1/10$) Common ($\geq 1/100$, $< 1/10$) Occasional ($\geq 1/1000$, $< 1/100$) Rare ($\geq 1/1000$, $< 10/1000$)

Very rare ($< 1/10\ 000$)

Not known (cannot be estimated from the available data)

Blood and lymphatic system disorders

Very rare: agranulocytosis, neutropenia, thrombocytopenia.

Immune system disorders

Very rare: hypersensitivity.

Nervous system disorders

Common: headache

Vascular disorders

Very rare: thrombo-embolism, hypotension.

Gastro-intestinal disorders

Common: nausea, abdominal discomfort, vomiting.

Skin and sub-cutaneous tissue disorders

Common: rash.

Musculoskeletal disorders

Rare: arthralgia.

General disorders and administration site conditions

Common: asthenia.

Very rare: fever.

In case of skin reactions or fever, the treatment must be stopped and the treating physician informed as this may constitute hypersensitivity reactions.

OVERDOSE

The symptoms of overdose are not known. In the event of any overdose, start symptomatic treatment.

PROPERTIES AND EFFECTS

ATC code: B02B X01

Other systemic haemostatics.

This drug is an antihaemorrhagic and vasoprotective agent: it increases platelet adhesiveness and restores capillary-wall resistance.

SPECIAL COMMENTS

STABILITY

The medicine must not be used after the date shown after the note « EXP » on the container.

PRECAUTIONS FOR STORAGE

Store below 30°C in the original pack protected from light. Do not use the DICYNONE 250 ampoules if the solution is colored.

PRESENTATION

Box of 4 or 10 ampoules

PRODUCT OWNER



OM Pharma SA, 22 rue du Bois-du-Lan, 1217 Meyrin, Switzerland

DATE OF LAST UPDATE

Oct 2014