For The Use of A Registered Medical Practitioner or A Hospital or A Laboratory

Rx

# Etamsylate Injection

AMERICAN

## Bleeduce Injection

**1 NAME OF THE MEDICINAL PRODUCT**

**BLEEDUCE INJ.** 2 ml Solution for Injection.

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Active ingredient is etamsylate 125mg/ml of injection solution. (250mg per 2 ml ampoule).

Water for Injection IP q.s.

**3 PHARMACEUTICAL FORM**

Solution for injection (injection).

Aclear, colourless, aqueous solution for injection (pH 6.2 to 6.8).

**4 CLINICAL PARTICULARS**

**4.1 Therapeutic Indications**

**BLEEDUCE injection** is indicated in neonates.

**BLEEDUCE injection** is used clinically for the prophylaxis and treatment of periventricular haemorrhage (bleeding into the brain immediately adjacent to cere bralventricles) in low birth weight infants (< 1.5 Kg).

**4.2 Posology and method of administration**

Neonates only :

The normal dosage is 12.5mg/kg body weight given by intravenous or intramuscular route within an hour of birth and every six hours for the first 4 days of life.

Clinical studies have not been performed in patients presenting hepatic or renal impairment. Consequently, caution is required when administering Dicynene injection to these patients.

**4.3 Contraindications**

Use in patients with a known hypersensitivity to etamsylate or to any of the excipients.

Acute porphyria

Bronchial asthma, confirmed hypersensitivity to sulphites.

**4.4 Special warnings and precautions for use**

Dicynene injection is intended for neonatal use only. If the infant develops a fever then treatment should be discontinued. Due to the risk of a fall in blood pressure during parenteral administration, caution is required in patients presenting unstable pressure or hypotension (see section 4.8 "undesirable effects").

**BLEEDUCE injection** solution contains sodium metabisulphite as antioxidant, which may cause allergic reactions, nausea and diarrhoea in susceptible patients.

The allergic reactions may go as far as anaphylactic shock and cause life threateningasthma 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 section 4.3 "Contraindications"). If a hypersensitivity reaction occurs, the administration of **BLEEDUCE injection** solution must be stopped immediately.

**4.5 Interaction with other medicinal products and other forms of interaction**

Dicynene injection is incompatible with solutions of sodium bicarbonate and compound sodium lactate.When Dicynene injection is mixed with saline it should be used immediately. Thiamine (vitamin B1) is inactivated by the sulphite contained in **BLEEDUCE injection**.If a dextran infusion is required, **BLEEDUCE injection** must be injected first.

**4.6 Fertility, pregnancy and lactation**

Clinical use is not relevant for this indication.There are no clinical data available concerning use in pregnant women. Animal experiments have not revealed any direct or indirect toxicity affecting pregnancy, embryonic development, foetal development and/or post-natal development. 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.

**4.7 Effects on ability to drive and use machines**

Not applicable in this population.

In adults, **BLEEDUCE injection** has no effect upon driving capacity and managing of machines.

**4.8 Undesirable effects**

In infants no major side-effects have been reported. In adults, the following side effects were described. These side effects are classified according to the MedDRA convention by system organ class and by frequency as follows:

Very common ( 1/10)

Common ( 1/100 to <1/10)

Uncommon ( 1/1 000 to <1/100)

Rare ( 1/10 000 to <1/1 000)

Very rare (<1/10 000), not known (cannot be estimated from the available data)

**Gastrointestinal disorders**

Common: nausea, diarrhoea, abdominal discomfort.

**Skin and subcutaneous tissue disorders**

Common: rash.

**General disorders and administration site conditions Common:**

asthenia

**Very rare:** fever.

**Nervous system disorders**

Common: headache.

**Vascular disorders**

Very rare: thromboembolism, hypotension.

**Blood and lymphatic system disorders**

Very rare: agranulocytosis, neutropenia, thrombocytopenia

**Musculoskeletal and connective tissue disorders**

Rare: arthralgia

Immune system disorders

Very rare: hypersensitivity

These reactions are generally reversible when stopping treatment course.In case of skin reactions or fever, the treatment must be stopped and the treating physician informed as this may constitute hypersensitivity reactions.

**4.9 Overdose**

There is no experience of over dosage with **BLEEDUCE injection**

In the event of any overdose, start symptomatic treatment.

**5 PHARMACOLOGICALPROPERTIES**

**5.1 Pharmacodynamic properties**

Other systemic haemostatics.

**BLEEDUCE injection** is a non-hormonal agent which reduces capillary exudation and blood loss. **BLEEDUCE injection** does not affect the normal coagulation mechanism since administration is without effect on prothrombin times, fibrinolysis, platelet countor function.

**BLEEDUCE injection** is thought to act by increasing capillary vascular wall resistance and platelet adhesiveness; in the presence of a vascular lesion, it inhibits the biosynthesis and action of those prostaglandins which cause platelet disaggregation, vasodilation and increased capillary permeability. Dicynene does not have a vasoconstricting action.

**5.2 Pharmacokinetic properties**

Following intravenous administration maximum blood levels of etamsylate are achieved in 2-3 minutes, while after intramuscular injection, maximum blood levels of etamsylate are achieved after about one hour. Etamsylate is excretedunchanged, largely by the urinary route.

**5.3 Preclinical safety data**

No further information is available.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Water for Injection IP q.s.

**6.2 Incompatibilities**

**BLEEDUCE injection** is incompatible with solutions of sodium bicarbonate and compound sodium lactate.

**6.3 Shelf life**Unopened: 2 years

Once opened: from a microbiological point of view the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are responsibility of the user and would normally not be longer than 24 hours at 2 to 8 oC, unless dilution has taken place in controlled and validated aseptic conditions

**6.4 Special precautions for storage**

Store below 25°C. Keep the ampoule in the outer carton.

**6.5 Nature and contents of container**

2 ml clear, Type I glass ampoules containing a colourless, sterile, aqueous solution.Outer cartons containing 10 X 2 ml ampoules.

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Discard if solution is coloured.

For single use only, any remaining solution should be discarded

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