

PACKAGE LEAFLET: INFORMATION FOR THE USER

This leaflet should be read by the parents of a baby receiving Dicycne Injection

Dicycne 250 mg/2 ml

Solution for injection

Etamsylate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dicycne is and what it is used for
2. Before you use Dicycne
3. How to use Dicycne
4. Possible side effects
5. How to store Dicycne
6. Further information

1. WHAT DICYNENE IS AND WHAT IT IS USED FOR

Dicycne Injection is available as a clear solution for injection in a 2ml ampoule containing 250 mg etamsylate, (125 mg per ml) which is the active ingredient.

Dicycne is a non-hormonal drug known as a haemostatic agent. It reduces the loss of fluid and blood from small blood vessels known as capillaries, and is particularly useful in low birth weight newborn.

It is used for the prevention and treatment of bleeding into the brain (periventricular haemorrhage) in newborns weighing less than 1.5kg.

2. BEFORE YOU USE DICYNENE

This product is intended for neonatal use only.

Do not use Dicycne:

- if the patient is allergic to etamsylate or any of the other ingredients of this medicine (listed in section 6).
- if the patient has porphyria (an illness characterized by a defect in the synthesis of haemoglobin).
- if the patient has asthma or is allergic to sulphites

If one of the above applies to your baby, the doctor will know what to do.

Warnings and precautions

Dicycne injection should be used with caution

- in case of liver or kidney dysfunction.
- in patients presenting unstable blood pressure or low blood pressure

If the newborn develops a fever then treatment should be discontinued.

Pregnancy and breast-feeding

Not relevant in this population.

In adults, 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.

Driving and using machines

Not applicable in this population.

In adults, Dicycne has no effect upon driving capacity and managing of machines.

Using other medicines

- Dicycne injection is incompatible with other medicines such as solutions of sodium bicarbonate and compound sodium lactate.
- Thiamine (vitamin B1) is inactivated by sulphite contained in Dicycne injection.

Important information about some of the ingredients of Dicycne

Dicycne injection contains sulphites which could cause allergic reactions, nausea and diarrhoea. These include anaphylactic symptoms and bronchospasm in susceptible patients.

If affected, likely symptoms are wheezing, shortness of breath, swelling and skin rashes, including hives (nettle rash).

This medicinal product contains less than 1 mmol sodium (23mg) per ampoule, i.e. essentially "sodium free".

3. HOW TO TAKE DICYNENE

The product is for use by the medical profession only. When Dicycylene injection is mixed with saline it should be used immediately.

If a dextran infusion is required, Dicycylene must be injected first.

Dosage

The normal use is 12.5 mg/kg body weight given intravenously or intramuscularly within an hour of birth, and every six hours for the first 4 days of life.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dicycylene can cause side effects, although not everybody gets them.

The following side effects have been reported during the use of Dicycylene:

Common (may affect up to 1 in 10 people):

- headaches
- skin rashes
- nausea
- diarrhoea
- abdominal discomfort
- feeling of weakness

Rare (may affect up to 1 in 1,000 people):

- joint pain

Very rare (may affect up to 1 in 10,000 people)

- fever
- fall in blood pressure
- coagulation disorders with blood clot formation

- severe reduction in number of white blood cells, making infections more likely
- reduction in blood platelets, which increases risk of bleeding or bruising
- allergic reaction

These reactions are generally reversible when treatment is stopped.

If skin reactions or fever occur, the treatment must be stopped and the doctor informed as these may indicate hypersensitivity reactions.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effect not listed in this leaflet.

The presence of sulphites may rarely cause severe hypersensitivity reactions and bronchospasm. If affected, likely symptoms are wheezing, shortness of breath, swelling and skin rashes, including hives (nettle rash).

The doctors and nurses will be monitoring your baby and you can talk to them if you have any worries.

5. HOW TO STORE DICYNENE

Keep the ampoule in the outer carton.

Store below 25°C. If the contents of the ampoule become coloured they should not be used.

Do not use this medicine after the expiry date which is stated on the ampoule and carton after "EXP". The expiry date refers to the last day of the month.

For single use only, any remaining solution should be discarded. Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What Dicycylene contains

- The active substance is etamsylate (250 mg per ampoule)
- Dicycylene Injection also contains the following ingredients: Sodium metabisulphite (E 223), Sodium hydrogen carbonate, water for injection.

What Dicycylene looks like and contents of the pack

Dicycylene are ampoules for injection use. Each carton of Dicycylene Injection contains 10 x 2 ml ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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