

PACKAGE LEAFLET: INFORMATION FOR THE USER

DICYNONE

250 mg tablets

ETAMSYLATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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

1. WHAT DICYNONE IS AND WHAT IT IS USED FOR

Dicynone contains etamsylate which is a medicine that stops bleeding (anti-hemorrhage agent). It reduces the time of bleeding and reduces the blood loss. This medicine is used in the prevention and treatment of capillary bleeding (bleeding from small blood vessels), regardless of the cause or localization of the bleeding.

Dicynone is administered in women with excessive or prolonged menstrual bleeding, caused by intrauterine devices, or by other factors.

2. BEFORE YOU TAKE DICYNONE

Do not take Dicynone:

- If you are allergic (hypersensitive) to etamsylate or any of the other ingredients of the medicinal product (listed in Section 6)
- If you are suffering from a rare blood disorders (Porphyria)

Warnings and precautions

Before taking Dicynone, contact your doctor or pharmacist if:

- you suffer from kidney failure (renal failure)
- you suffer from liver failure (hepatic failure)

Prior to initiation of treatment due to excessive and/or prolonged menstrual bleeding, your doctor will send you to a detailed gynecological examination, and it is necessary to follow his/her instructions.

If in spite of the application of Dicynone your condition does not improve, it is necessary that you inform your doctor, so that he/she can exclude any organic cause.

Taking other medicines with Dicynone

Please inform your doctor or pharmacist if you are taking, if you've recently taken, or you could be taking any other medicine.

There are no data about the interaction of medicines.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, you think you may be pregnant, or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide if you can take Dicynone during pregnancy.

It is not known whether the etamsylate is excreted into breast milk; as a precaution, nursing women should not take this medicine.

Driving and using machines

Etamsylate does not affect the ability to drive or use machines.

Dicynone contains lactose.

If your doctor said that you have intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE DICYNONE

Always take Dicynone exactly as recommended by a doctor. If you have questions, please consult a doctor or pharmacist.

Adults and adolescents:

The usual dose is 2 Dicynone tablets 2-3 times a day, taken with meals with a small amount of water. Your doctor will decide the dose and length of treatment, depending on the severity and progression of the disease.

In case of excessive menstrual bleeding 2 Dicynone tablets are taken 3 times a day with meals with a small amount of water. Treatment starts 5 days before the expected start of the menstrual cycle and lasts for 10 days.

Use in children

In children, half the adult dose is applied, i.e. 1 tablet 2-3 times a day.

Do not change the dose that is prescribed to you. If you believe that the effect of Dicynone is too strong or too weak, talk to your doctor or pharmacist.

If you take more Dicynone than you should

If you think you have taken too much medicine, inform your doctor.

If you forget to take Dicynone

Do not take a double dose to make up for the missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines Dicynone may cause side effects, although not everybody gets them.

If you notice any of the following rare but very serious side effects, stop taking this medicine and tell your doctor:

- Sudden shortness of breath, swelling of the lips, tongue and throat, or body, rash, fainting, or difficulty swallowing (severe allergic reaction)
- Swelling, redness and pain in one part of the body, usually in the leg (thromboembolism)

Side effects are listed according to the following categories of frequency:

Very common: occurs in more than 1 in 10 patients who take the medicine

Common: occurs in 1 to 10 in 100 patients

Uncommon: occurs in 1 to 10 in 1000 patients

Rare: occurs in 1 to 10 to 10000 patients

Very rare: occurs in less than 1 in 10000 patients

Unknown frequency: cannot be estimated on the basis of the available data

Common side effects:

- headache
- nausea, diarrhea, stomach discomfort
- rash
- feeling of weakness

Rare side effects:

- pain in the joints

Very rare side effects:

- fever
- blockage of the blood vessels and blood by blood clot formed elsewhere in the body (venous thromboembolism)
- blood disorders such as a reduction in the number of white blood cells or platelets, which can cause bleeding or the appearance of bruises, or increase in the frequency of infections.
- Hypersensitivity

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.

5. HOW TO STORE DICYNONE

Keep out of reach and sight of children.

Keep at temperature below 25 ° c.

Store in the outer carton in order to protect the product from direct sunlight and moisture.

Shelf life: 5 years

If the "shelf life" as stated on the blister or container has expired, Dicynone should not be used. The medicine can be used up to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. FURTHER INFORMATION

What does Dicynone contain?

The active substance is etamsylate. Each tablet contains 250 mg of etamsylate.

The other ingredients:

Anhydrous citric acid, corn starch, lactose monohydrate, povidone K25, magnesium stearate.

How Dicynone looks like and contents of the pack

Tablets are white, round, convex.

Dicynone 250 mg tablets are packed in Al/PVC/PVDC blister packs of 10 tablets. Cardboard box containing 30 tablets.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

Lek farmacevtska družba d.d.

Verovškova 57, Ljubljana, Republic of Slovenia

Manufacturer of the medicinal product

Lek farmacevtska družba d.d. (in collaboration with OM Pharma, Switzerland)

Verovškova 57, Ljubljana, Republic of Slovenia