

## **Information for the patient**

Read all of this package leaflet carefully before you start taking or using this medicine. This medicine has been prescribed for you only. Do not pass it on to others, even if their symptoms seem to be the same as yours. This medicine could actually harm them. Keep this package leaflet. You may need to read it again.

### **DICYNONE 500 capsule**

#### **What is Dicynone 500 capsule and when should it be used?**

Dicynone 500 capsule is a haemostatic medicine, able to reduce bleeding time and loss of blood.

Dicynone 500 capsule is prescribed by your doctor to prevent and treat capillary haemorrhages (haemorrhages of the very small blood vessels), regardless of their origin or location.

Dicynone 500 capsule is also prescribed to patients suffering from excessively heavy or long periods, whether due to wearing an intrauterine device or not.

#### **What do you need to know before treatment?**

Before starting treatment for excessively heavy and/or long periods, your doctor will carry out a thorough gynaecological examination and it is essential that you follow your doctor's instructions.

#### **When should Dicynone 500 capsule not be used?**

You should not take Dicynone 500 capsule if you have a rare blood disorder (porphyria). Your doctor will know what to do in this situation.

The capsules, which contain 500 mg of active substance, are unsuitable for treating children. Hypersensitivity (allergy) to one of the ingredients.

#### **What precautions should be taken when taking Dicynone 500 capsule?**

Only your doctor can decide if you can take Dicynone 500 capsule if you suffer from kidney or liver function disorders.

If Dicynone 500 capsule has been prescribed to you to alleviate excessively heavy and/or long periods and the treatment does not cause an improvement, you should notify your doctor immediately so that any organic abnormalities can be excluded.

Please tell your doctor or pharmacist if

- you will be undergoing medical examinations: during treatment with etamsylate, if a sample (e.g. a blood sample) is required for laboratory tests it must be taken before the first daily administration of the medicine in order to minimise any potential interaction between etamsylate and the laboratory tests;
- you are suffering from another illness;
- you are allergic; or
- you are taking other medicines (including any you are taking without a prescription).

Dicynone 500 has no effect on the ability to drive or use machines.

### **Can Dicynone 500 capsule be taken/used during pregnancy or breast-feeding?**

If you are pregnant, are planning to have a baby or if you are breast-feeding, as a precaution, you should avoid taking medicines.

There are limited data available on the use of Dicynone 500 capsule in pregnant women.

Etamsylate crosses the placental barrier: maternal blood and cord blood contain similar concentrations of etamsylate.

Etamsylate must not be used during pregnancy unless absolutely necessary.

As it is not currently known whether Dicynone 500 capsule passes into breast milk, as a precaution, it should not be used by breast-feeding mothers.

### **How is Dicynone 500 capsule taken?**

Reserved for adults and adolescents.

Generally, 1 capsule, 2 to 3 times a day, to be taken with a little water during meals. The doctor will decide the dose and duration of treatment based on the illness and results obtained.

For excessively heavy periods, 1 capsule, 3 times a day, to be taken with a little water during meals. The treatment starts 5 days before the period is expected to start and lasts 10 days (see “*What precautions should be taken?*”).

#### **Children**

Dicynone 500 (tablet or capsule) is not appropriate for treating children.

Do not change the prescribed dose on your own initiative. If you think that the effect of this medicine is too weak or too strong, talk to your doctor or pharmacist.

### **What side effects can be caused by Dicynone 500 capsule?**

Taking or using Dicynone 500 capsule can cause the following side effects:

*Common:* stomach upset, diarrhoea, nausea, headache, skin rashes, fatigue

*Rare:* joint pain

*Very rare:* fever, allergic reactions

The most serious side effects are:

*Very rare:* coagulation disorders with a clot in the blood vessels, severe reduction in the number white blood cells which makes infections more likely, reduced number of blood platelets which increases risk of bleeding or bruising.

In most cases, these side effects disappear when treatment is stopped.

If they persist or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If skin reactions or fever occur, treatment should be discontinued and the doctor should be informed, as this may constitute an allergic reaction.

### **Other things you need to know**

Store at temperature below 30°C in a dry place out of the reach of children.

It should not be used after the date which is stated on the container after “EXP”.

For more information, talk to your doctor or pharmacist, who will have more detailed information aimed at health professionals.

**What does Dicynone 500 capsule contain?**

One capsule of Dicynone 500 capsule contains 500 mg of etamsylate, as well as other ingredients.

**Where can you get Dicynone 500 capsule?**

**What pack sizes are available on the market?**

In pharmacies, with a medical prescription.

Dicynone 500 capsules (500 mg): packs of 20 and 60 capsules.

**Marketing Authorisation Holder/Manufacturer**

OM Pharma SA, rue du bois du Lan 22, CH-1217 Meyrin, Switzerland.

**This package leaflet was last approved by the medicines control authority (Swissmedic) in July 2016.**