1. Trade name of the medicinal product
DICYNONE 500

2. Qualitative and quantitative composition
Active principle: Etamsylate 500 mg
For excipients, see section 6.1.

3. Pharmaceutical form
Tablets.

4. Clinical particulars
4.1. Therapeutic indications
In surgery:
Prevention and treatment of pre- or postsurgical capillary haemorrhages in all delicate operations and in those affecting highly vascularised tissues: E.N.T., gynecology, obstetrics, urology, odontostomatology, ophthalmology, plastic and reconstructive surgery.

In internal medicine:
Prevention and treatment of capillary haemorrhages of whatever origin or localisation: haematuria, hematemesis, melaena, epistaxis, gingivorrhagia.

In gynecology:
Menorrhagia, primary or IUD-related menorrhagia in the absence of organic pathology.

4.2. Posology and method of administration
Adults: Oral route.
Presurgical: 1 tablet (500 mg) 1 hour before surgery.
Postsurgical: 1 tablet (500 mg) every 4-6 hours as long as the risk of bleeding persists.

Internal medicine: generally 1 tablet 2-3 times a day (1000-1500 mg) to be taken with meals with a little water; treatment duration depends on the results obtained.

Gynecology, meno-metrorrhagia: 1 tablet 3 times a day (1500 mg) to be taken with meals with a little water. Treatment lasts 10 days and starts 5 days before the expected onset of menses.

Children
Because of its high concentration of active principle,Dicynone 500 is not appropriate for children.

4.3. Contra-indications
Acute porphyria.
Hypersensitivity to the active substance or to any of the excipients.
Bronchial asthma, proven hypersensitivity to sulphites.

4.4. Special warnings and special precautions for use
If Dicynone 500 is administered for a reduction of excessive and/or prolonged menstrual haemorrhages, and no improvement is observed, possible pathological causes should be looked for and excluded.

4.5. Interactions with other medicinal products and other forms of interaction
No interaction is known up to now.

4.6. Pregnancy and lactation
Pregnancy category C: For etamsylate, no clinical data on exposed pregnancies are available.
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see 5.3.). As a precaution, Dicynone should not be administered during the first trimester of pregnancy, whereas during the second and third trimester, it should be administered only if the expected therapeutic benefit is judged as superior to the potential risk for the foetus.

In the absence of data regarding passage into maternal milk, lactation during treatment is not advisable or, if lactation is to continue, the treatment must be stopped.

4.7. Effects on ability to drive and use machines
Dicynone 500 tablet has no effect on the ability to drive and use machines.

4.8. Undesirable effects
Rare: gastralgia, nausea, headache, skin rash.
In most cases, these symptoms disappear spontaneously.
Kinetics in particular situations
It is not known if the pharmacokinetic properties of etamsylate are modified in patients suffering from renal and/or hepatic function disorders.

5.3. Preclinical safety data
Acute and chronic toxicity studies, foetotoxicity and mutagenicity studies on etamsylate have not revealed any toxic effect.

6. Pharmaceutical particulars

6.1. List of excipients
Maize starch, microcrystalline cellulose, povidone, stearic acid, sodium dihydrogen citrate, anhydrous sodium sulfite.

6.2. Incompatibilities
No known up to now.

6.3. Shelf-life
The medication should not be used after the expiration date printed on the package together with the mention “EXP”.

6.4. Special precautions for storage
To be stored protected from heat (below 30°C).

6.5. Nature and content of container
Boxes containing blister-packs of 10 tablets. (Aluminium foil lacquered with PVDC-PVC/PVDC foil)

6.6. Instructions for use
No special instructions.

7. Marketing Authorization Holder
OM PHARMA, 22, rue du Bois-du-Lan, 1217 Meyrin 2 / Geneva (Switzerland)