SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sylate 500 tablet (Etamsylate 500 mg tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Etamsylate BP ..... 500 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Uncoated Tablets
A faint pink, capsule-shaped, elongated, uncoated tablet. The tablet is flat on both sides with a score line on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Used in the symptomatic treatment of functional disorders of capillary fragility.
Adjunctive treatment of menorrhagia after etiological assessment.

4.2 Posology and method of administration

Adults
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, Etamsylate is not appropriate for children.

Method of
administration
Route of
administration: Oral

4.3 Contraindications

Acute porphyria.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 Bronchial asthma, proven hypersesnsitivity to sulphites.

4.4 Special warnings and precautions for use

If etamsylate 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.
Several cases of isolated fever that occurred upon resumption of treatment have been reported with Etamsylate. If fever develops, treatment should be stopped and not restarted.
In the absence of information on the safety of Etamsylate in patients with acute porphyria, this drug is not recommended in these patients.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction is known up to now.

4.6 Pregnancy and lactation

Pregnancy
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. As a precaution, Sylate 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.
Breast-feeding
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:

Etamsylate has no effect on the ability to drive and use machines.

4.8 Undesirable effects:

The side effects of etamsylate are listed below by frequency.
Frequencies are defined as: very common (≥1/l0), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥ 1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports, not known (cannot be estimated from the available data)
Rare: gastralgia, nausea, headache, skin rash.
In most cases, these symptoms disappear spontaneously. If they persist, the dosage should be reduced or the treatment withdrawn.

Etamsylate tablets contain sulphite as antioxidant that may cause allergic reactions, nausea and diarrhea in susceptible patients. The allergic reactions may lead to anaphylactic shock and cause life-threatening asthma attacks. The incidence in the population is not known but is probably low. However, hypersensitivity towards sulphite is observed more frequently in asthmatics than in nonasthmatics. In case of hypersensitivity reactions, the administration of Etamsylate must be immediately stopped.

Healthcare professionals are requested to report any suspected adverse

reactions via the Pharmacy and Poisons Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

No case of overdose has been reported. In case of overdosage, a symptomatic treatment should be initiated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other systemic hemostatics ATC code: B02BX01

Etamsylate is a synthetic antihaemorrhagic and angioprotective drug acting on the first step of haemostasis (endothelium-platelet interaction). By improving platelet adhesiveness and restoring capillary resistance, it is able to reduce bleeding time and blood losses.

Etamsylate has no vasoconstrictor action, it does not influence fibrinolysis nor modify the plasma coagulation factors.

5.2 Pharmacokinetic properties

When given p.o., etamsylate is slowly absorbed from the gastrointestinal tract. After oral administration of 500 mg etamsylate maximum plasma level, i.e. 15 µg/ml, is reached at 4 h, but bioavailability is not known. The binding rate to plasma proteins is about 95%. Plasma half-life is about 3, 7 h. About 72% of the administered dose are excreted in the first 24 h-urine; the molecule is excreted unchanged. Etamsylate crosses the placental barrier. Maternal and cord blood contains similar concentrations of etamsylate. It is not known if etamsylate is excreted in the maternal milk.

Kinetics in special population Renal or hepatic patients

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 excipient(s)

Microcrystalline Cellulose
Crospovidone polyplasdone XL 10
Sodium Starch Glycolate
Color Iron Oxide Red
Sodium Lauryl Sulphate
Disodium EDTA

Sodium
metabisulphite
Povidone [PVPK-
30]
Isopropyl Alcohol
Colloidal Silicon
Dioxide
Purified water
Magnesium
Stearate
Crospovidone polyplasdone
XL 10
Talc

6.2 Incompatibilities

None of the In-active ingredients of the formulation have been known to exhibit incompatibility with the Active ingredient.

6.3 Shelf-life

24 months

6.4 Special precautions for storage

Store in a cool dry place, below 30°C

6.5 Nature and contents of container

A Faint pink colored capsule shaped uncoated tablet with a break line on one side and plain on another side.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Emcure Pharmaceuticals Ltd.
Plot No. P-1 & P-2, I.T. B.T. Park
Phase-II, M.I.D.C, Hinjwadi, Pune –
411057, India

8. MARKETING AUTHORISATION NUMBER(S)

12985

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19.04.2011

10. DATE OF REVISION OF THE TEXT

November 2025