SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Sylent 500 Tablets (Etamsylate Tablets 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active ingredient: Etamsylate
Each uncoated tablet contains:
Etamsylate BP 500 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablet
White, circular, biconvex, un-coated, scored tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Etamsylate is indicated for use in adults.
In surgery: Prevention and treatment of pre- or postsurgical capillary haemorrhages in all type of delicate operations and in those affecting highly vascularised tissues: E.N.T, gynaecology, obstetrics, urology, stomatology, ophthalmology, plastic and reconstructive surgery.
In internal medicine: Prevention and treatment of capillary haemorrhages of whatever origin or localisation: haematuria, haematemesis, melaena, epistaxis, gingivorrhagia.
In gynaecology: Metrorrhagia, primary or IUD-related menorrhagia in the absence of organic pathology.

4.2 Posology and method of administration
Posology
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). Treatment duration depends on the results obtained.
Gynaecology: In the case of menorrhagia or metrorrhagia, 1 tablet 3 times a day (1500 mg). Treatment lasts 10 days and starts 5 days before the expected onset of menses.
Paediatric population: Because of its high concentration, Etamsylate is not intended for administration for children.
Special population: No clinical studies have been conducted in patients with impaired hepatic or renal function. Therefore, caution should be exercised in administrating Etamsylate in those patients.
Method of administration
Oral route.
Tablets should be taken with meals with a drink of water (except for administration prior to surgery, when Etamsylate is administered on an empty stomach).

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
It is contraindicated in pregnancy & lactation.

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.

Excipients
This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction
There are no known interactions with other medical products.
Etamsylate at therapeutic doses may interfere with enzymatic assay of creatinine, as well as lactate, triglycerides, uric acid and cholesterol. The obtained values are lower than expected for up to 12 hours. These observations were based on the studies with intravenous administered etamsylate. During the course of etamsylate treatment, sample collection (e.g. blood sampling) required for laboratory testing, should be done before the first administration of the drug in order to minimize any potential interaction of etamsylate with laboratory testing.

4.6 Fertility, pregnancy and lactation
Pregnancy: There are no or limited amount of data from the use of Etamsylate in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precaution, etamsylate should not be administered during the first trimester of pregnancy, whereas during the second and third trimesters, it should be administered only if the expected therapeutic benefit is judged as superior to the potential risk for the foetus.
Lactation: There is insufficient information on the excretion of etamsylate in human milk. Therefore, breast-feeding during treatment is not advisable, or if lactation is to continue, the treatment must be stopped.
Fertility: No data available.

4.7 Effects on ability to drive and use machines
Etamsylate has no influence on the ability to drive and use machines.

4.8 Undesirable effects

System Organ Class	**Very Common (≥1/10)**	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1,000)**	**Very Rare (<1/10,000)**	**Not Known**
Gastrointestinal disorders	–	Abdominal pain, nausea, diarrhea, vomiting, abdominal discomfort	–	–	–	–
Nervous system	–	Headache	–	–	–	–

disorders						
Skin and subcutaneous tissue disorders	–	Rash	–	–	–	–
General disorders and administration site conditions	–	Weakness	–	–	Fever	–
Vascular disorders	–	–	–	–	Thromboembolism	–
Blood and lymphatic system disorders	–	–	–	–	Agranulocytosis, neutropenia, thrombocytopenia	–
Musculoskeletal and connective tissue disorders	–	–	–	Arthralgia	–	–
Immune system disorders	–	–	–	–	Hypersensitivity reactions	–

Frequency Categories: Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

These adverse reactions are usually reversible when treatment is discontinued.
In case of adverse skin reaction or fever, it is necessary to immediately discontinue the treatment and inform doctor as it may be the first signs of hypersensitivity. Upon the occurrence of repeated vomiting, lasting more than 2 days, the treatment must be stopped.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System
(PvERS) https://pv.pharmacyboardkenya.org'

4.9 Overdose
Symptoms of overdose are unknown. In case of overdose, a symptomatic treatment should be initiated.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antihemorrhagics, 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

Absorption

When given *p.o.*, etamsylate is slowly and fully 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, bioavailability is not known.

Distribution

The binding rate to plasma proteins is about 95%.

Elimination

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. There is insufficient information on the excretion of etamsylate in human milk.

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

Dibasic Calcium Phosphate, Sodium Starch Glycolate, Copovidone (PVPK30), Purified Talc, Magnesium Stearate

6.2 Incompatibilities

Not known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a cool, dark & dry place. Protect from light.

Keep all medicines out of reach or children

6.5 Nature and contents of container

Aluminium-aluminium strip packing.

Pack sizes: 2 strips 10 tablets each.

6.6 Special precautions for disposal and other handling

No special requirements however any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORIZATION HOLDER ADDRESSE

Name and permanent address or registered place of business of the Marketing Authorization Holder and manufacturing site(s) physical address.

MANUFACTURING SITE ADDRESSE

Name and Permanent	Zest Pharma

address	Plot No. 275, Sector “F” Sanwer Road, Indore 452 015 (M.P.) INDIA
Telephone No.:	+91 731 4252911/912
Fax No.:	+91 731 2722766
Email:	info@zestpharma.in,

8. MARKETING AUTHORIZATION NUMBER

16787

9. DATE OF FIRST REGISTRATION/ RENEWAL OF THE REGISTRATION

Date of first authorization: 14/02/2007
Date of latest renewal: 20/12/2022

10. DATE OF REVISION OF THE TEXT

11/06/2026