For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

STYPTOVIT E

1. GENERIC NAME

Etamsylate Tablets

2. Qualitative and Quantitative COMPOSITION

STYPTOVIT-E

Each uncoated tablet contains:

Etamsylate B.P. …… 250 mg

The excipients used are Microcrystalline cellulose, Starch, Sodium Benzoate, Polyvinyl Pyrrolidone, Magnesium Stearate, Talcum, Sodium starch glycolate, Colloidal Silicon Dioxide.

3. DOSAGE FORM AND STRENGTH

DOSAGE: uncoated Tablet

STRENGTH: 250 mg

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Anti-haemostatic Indicated in the treatment of small vessel haemorrhage menorrhagia (including IUD users) prophylaxis of periventricular haemorrhage in neonates.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Dosage: As directed by the Physician

4.3 CONTRAINDICATIONS

Acute porphyria.

Hypersensitivity to the active substance or to any of the excipients.

Bronchial asthma, proven hypersesnitivity to sulphites.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

If Styptovit E 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 DRUG INTERACTION

No interaction is known up to now.

4.6 USE IN SPECIAL POPULATION

Pregnancy category C: For etamsylate, no clinical data on exposed pregnancies are available.

In reported animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/ foetal development, parturition or postnatal development. As a precaution, Styptovit E 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

Styptovit E 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.

If they persist, the dosage should be reduced or the treatment withdrawn.

Styptovit E tablets contains 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 Styptovit E tablets must be immediately stopped.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting

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

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 250 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 particular situations

It is not known if the pharmacokinetic properties of etamsylate are modified in patients suffering from renal and/or hepatic function disorders.

6. NON-CLINICAL PROPERTIES

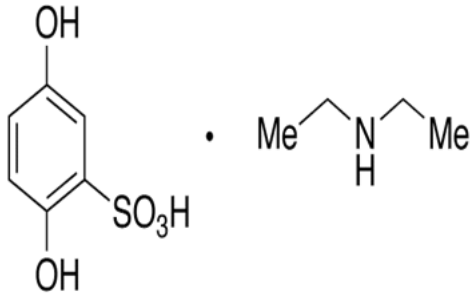
6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

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

7. DESCRIPTION

Etamsylate

Etamsylate is 2,5-Dihydroxybenzenesulfonic Acid N-Ethylethanamine Salt; 2,5-Dihydroxybenzene. The empirical formula is $C_{10}H_{17}NO_5S$ and its molecular weight is 190.17. Its structural formula is:



Etamsylate tablets are White, round, biconvex, plain on both sides & uncoated tablets.

The excipients used are Microcrystalline cellulose, Starch, Sodium Benzoate, Polyvinyl Pyrrolidone, Magnesium Stearate, Talcum, Sodium starch glycolate, Colloidal Silicon Dioxide.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

Not available

8.2 Shelf Life

Do not use later than date of expiry

8.3 Packaging Information

Styptovit E is available in pack of 10 Tablets

8.4 Storage and handling instructions

Store protected from light & moisture, at a temperature not exceeding 30°C.

9. PATIENT COUNSELLING INFORMATION

Package leaflet: Information for the user

STYPTOVIT E

Etamsylate Tablets 250 mg

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?

9.1. What STYPTOVIT E is and what it is used for

STYPTOVIT E contain Etamsylate 250 mg. and it is used for the treatment of small vessel haemorrhage menorrhagia (including IUD users) prophylaxis of periventricular haemorrhage in neonates.

9.2. What you need to know before you take STYPTOVIT E

Do not take STYPTOVIT E

If you are allergic to Styptovit E hydrochloride or any of the other ingredients of this medicine;

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Styptovit E

If Styptovit E 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.

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, Styptovit E 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.

9.3. How to take STYPTOVIT E.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you take more STYPTOVIT E

If you take more Styptovit E, contact your doctor immediately or go to your nearest hospital. Take this package leaflet to your doctor.

If you forget to take STYPTOVIT E

If you forget to take a dose, take your next dose at the usual time and then keep taking your medicine as told by your doctor. Do not take a double dose to make up for a forgotten dose.

If you stop taking STYPTOVIT E

If you stop taking your medicine Please contact your doctor or pharmacist if you have any questions regarding the use of this medicinal product.

9.4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare: gastralgia, nausea, headache, skin rash.

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9.5. How to store STYPTOVIT E

Store protected from light & moisture, at a temperature not exceeding 30°C.

9.6 Contents of the pack and other information

STYPTOVIT E (Etamsylate)

Etamsylate B.P. 250 mg The excipients used are Microcrystalline cellulose, Starch, Sodium Benzoate, Polyvinyl Pyrrolidone, Magnesium Stearate, Talcum, Sodium starch glycolate, Colloidal Silicon Dioxide.

STYPTOVIT E is available in pack of 10 tablets

10. DETAILS OF MANUFACTURER

Pure & cure Healthcare Pvt. Ltd.

(A subsidiary of Akums Drugs & pharmaceuticals Ltd.),

Plot No. 26A,27-30,Sector -8A,I.I.E.,SIDCUL,

Ranipur, Haridwar -249 403, Uttarakhand

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Mfg. Lic. No.: 31/UA/2013 issued on 26.08.2014

12. DATE OF REVISION

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/STYPTOVIT E 250 mg/FEB-23/01/PI