

Package leaflet: Information for the patient

{Product name}
500 mg, capsules, hard

Etamsylate

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet

1. What {Product name} is and what it is used for
2. What you need to know before you take {Product name}
3. How to take {Product name}
4. Possible side effects
5. How to store {Product name}
6. Contents of the pack and other information

1. What {Product name} is and what it is used for

{Product name} is an antihemorrhagic drug, which reduces bleeding time and blood losses.

The medicine {Product name} is used to prevent and treat bleeding from the small tubes (vessels), irrespective of the cause and location of the bleeding.

The medicine {Product name} is used to treat spotting (bleeding between the expected menstrual periods) and treat heavy or prolonged bleeding during a menstrual period, in connection with or independently of the use of intrauterine contraceptive device (IUCD).

2. What you need to know before you take {Product name}

Do not take {Product name}

- if you are allergic to etamsylate or any of the other ingredients of this medicine (listed in section 6).
- if you have porphyria (an illness characterized by a defect in the synthesis of hemoglobin). In this case, tell a doctor, who will know what to do.

Warnings and precautions

Talk to your doctor or pharmacist before taking {Product name}:

- if you are about to have medical examinations: during the course of {Product name} 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 {Product name} with laboratory testing.
- if you are a woman, you must have a gynaecological examination before you can start taking {Product name} for menstrual bleeding.

Children

{Product name} is not intended for administration for children.

Other medicines and {Product name}

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

{Product name} with food and drink

The medicine may be taken with meals with a drink of water (except for administration prior to surgery, when the medicine is administered on an empty stomach).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There are limited amount of data from the use of {Product name} in pregnant women.

Animal studies do not indicate any direct or indirect toxic effects on pregnancy, embryonic and foetal development and/or postnatal development.

As a precautionary measure, it is preferable to avoid the use of {Product name} during pregnancy.

Breast-feeding

As there are no data available on whether the medicine is excreted in human milk, breast-feeding is not recommended during treatment. Alternatively, if breast-feeding is to continue, treatment must be stopped.

Fertility

No data available.

Driving and using machines

In adults medicine {Product name} has no effect on the ability to drive and use machines.

3. How to take {Product name}

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

{Product name} is intended for adults. The medicine is administered orally.

Internal medicine: generally 1 capsule 2-3 times a day (1000-1500 mg). Medical product should be taken with meals with a drink of water. Treatment duration depends on the results obtained.

Presurgical: 1 capsule (500 mg) 1 hour before surgery.

Postsurgical: 1 capsule (500 mg) every 4-6 hours as long as the risk of bleeding persist.

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

If {Product name} 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. You should immediately consult your doctor who will carry out research and determine the further course of treatment.

{Product name} should be used with caution in case of hepatic and renal dysfunction.

Use in children

{Product name} is not intended for administration for children.

If you feel that the effect of {Product name} is too strong or too weak, talk to your doctor or pharmacist. Never stop taking the medicine without informing your doctor or pharmacist.

If you take more {Product name} than you should

Inform your doctor or pharmacist immediately. In case of overdose, treatment of symptoms must be initiated.

If you forget to take {Product name}

Do not take a double dose to make up for a forgotten capsule.

Inform your doctor or pharmacist, who will recommend the next steps.

If you stop taking {Product name}

No known effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common (may affect up to 1 in 10 people):

- headache,
- rash,
- abdominal pain, nausea, diarrhea, vomiting, discomfort in the abdomen,
- feeling of weakness.

Rare (may affect up to 1 in 1 000 people):

- joint pain.

Very rare (may affect up to 1 in 10 000 people):

- fever,
- coagulation disorders with formation of clot in vessels (thromboembolism),
- severe reduction in number of white blood cells which makes infections more likely,
- reduction in blood platelets, which increases risk of bleeding or bruising,
- allergic reaction.

These reactions are generally reversible when stopping treatment course. In the case of skin reaction or fever, the treatment must be stopped and the doctor must be informed as this may constitute hypersensitivity reactions. Upon the occurrence of repeated vomiting, lasting more than 2 days, the treatment must be stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via <[To be completed nationally]>.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store {Product name}

Store below 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after: {abbreviation used for expiry date} or on the blister after: {abbreviation used for expiry date}. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What {Product name} contains

- The active substance is etamsylate 500 mg.
- The other ingredients are: stearic acid, titanium dioxide (E 171), erythrosine (E 127), quinoline yellow (E 104), gelatin.

What {Product name} looks like and contents of the pack

The medicine {Product name} is available in hard capsules. The capsule is cylindrical-oval, closed, two-part and orange. The content of the capsule is a white or almost white powder.

Packaging size:

30 unit dose – 3 blister packs of 10 unit dose,

60 unit dose – 6 blister packs of 10 units dose.

PVC/PVDC/Aluminium blisters in cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Farmaceutyczna Spółdzielnia Pracy „GALENA”

Krucza 62

53-411 Wrocław

Poland

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>