1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hemosilate 125 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Etamsylate 125 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
Sodium metabisulfite (E223)	0.4 mg
Sodium sulfite anhydrous (E221)	0.3 mg
Disodium edetate	
Water for injection	

Clear and colourless solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, goats, pigs, horses, dogs and cats.

3.2 Indications for use for each target species

Prevention and treatment of surgical, post traumatic, obstetric and gynecological haemorrhages.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of surgical or traumatic rupture of large blood vessels, it is necessary to ligate the affected vessels to block blood flow prior to etamsylate administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Etamsylate, sulfites and benzyl alcohol may cause hypersensitivity (allergic) reactions. Symptoms may include nausea, diarrhoea and skin rashes. People with known hypersensitivity to etamsylate or any of the excipients, or those with asthma, should avoid contact with the veterinary medicinal product.

Administer this veterinary medicinal product with caution to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product may cause skin and eye irritation. In case of accidental skin or eye contact, wash the affected area thoroughly.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep, goats, pigs, horses, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis

*due to the presence of sulfites.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and mice have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intravenous or intramuscular use.
5 to 12.5 mg of etamsylate/kg bw, equivalent to 0.04 to 0.1 ml/kg bw of the veterinary medicinal product, according to the severity of the procedure/haemorrhage.

Treatment is normally made until the desired effect is reached; it may be for one day but could be repeated for a further 2 to 3 days in order to obtain control of the bleeding
For prevention of surgical bleeding the product should be administered at least 30 minutes before surgery.

For treatment of an ongoing haemorrhage, the product can be administered up to every 6 hours until bleeding has stopped completely.

In case of rupture of large blood vessels, it is necessary to ligate the affected vessels before administering this veterinary medicine.

Do not administer more than 20 ml of this product in a single injection site. Each injection should be given at a different site.
The stopper should not be punctured more than 25 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Cattle, Sheep, Goats and Horses:
Meat and offal: After intravenous (i.v.) administration: Zero days.
After intramuscular (i.m.) administration: 1 day.
Milk: Zero hours.

Pigs:
Meat and offal: After intravenous (i.v.) administration: Zero days.
After intramuscular (i.m.) administration: 1 day.

4. PHARMACOLOGICAL PARTICULARS

4.1 ATCvet code:
QB02BX01

4.2 Pharmacodynamics

Etamsylate is a hemostatic and angioprotective drug that stimulates platelet adhesiveness shortening bleeding time and normalizing rapidly and lastly the altered vascular fragility and permeability.

Its mechanism of action is attributed to the inhibition of prostacyclin (PGI_2) synthesis that causes the platelet disaggregation, vasodilation and increase of capillary permeability and to the activation of P-selectine, which facilitates the interaction between platelets, leucocytes and endothelium. It acts on primary hemostasis without affecting prothrombin time, fibrinolysis or platelet count.

In animal models of capillary bleeding, the administration of etamsylate shortens bleeding time and the severity of the hemorrhage up to 50% reaching its maximum effect between 30 minutes and 4 hours after its administration.

4.3 Pharmacokinetics

In all the species studied, after an intravenous administration, etamsylate shows a limited tissue distribution, substantiated by a low Volume of Distribution (Vd: 0,4; 0,36 and 0.44 L/kg in dogs, cats

and cattle respectively) due to its low liposolubility. Therefore, its action is practically limited to the circulatory system and blood vessels of highly irrigated organs. It is eliminated rapidly from the body with an elimination Half Life ($T_{1/2}$) of 1,14; 0.75 and 1.24 h in dogs, cats and cattle, respectively, via urine, practically unaltered.

When administered intramuscularly, etamsylate is absorbed very rapidly and almost completely (F: 97.5; 99.8 and 98.4 % in dogs, cats and cattle respectively). Etamsylate reaches the maximum blood concentrations (C_{max}: 27; 25.8 and 10,7 µg/ml in dogs, cats and cattle respectively) approximately 1h after its administration (T_{max}: 0.42; 0.54 and 1.3 h in dogs, cats and cattle respectively).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening the immediate packaging: 14 days

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Amber glass type I vial containing 20 ml, with type I chlorobutyl stopper and flip-off aluminum cap in a carton box.

Pack sizes:
Box with 1 vial of 20 ml
Box with 5 vials of 20 ml
Box with 10 vials of 20 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10389/004/001

8. DATE OF FIRST AUTHORISATION

30 August 2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

08 April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).