Summary of Product Characteristics

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:

Benzyl alcohol (E1519)	10	mg
Sodium metabisulfite (E223)	0.4	mg
Sodium sulfiteanhydrous (E221)	0.3	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear and colourless solution, free from visible particles.

4 CLINICAL PARTICULARS

4.1 Target Species

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

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 product.
- Administer this 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 product may cause skin and eye irritation. In case of accidental skin or eye contact, wash the affected area thoroughly.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic reactions to similar products have been reported in humans due to the presence of sulfites. It is possible that similar reactions may occur in the target animal species.

4.7 Use during pregnancy, lactation or lay

Laboratory studies performed with rats and mice have not demonstrated any teratogenic or toxic effect to the fetus or the mother. The safety of the product has not been established in the target species during pregnancy and lactation.
Use only according to a benefit/risk evaluation performed by the veterinary responsible.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For 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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Cattle, sheep, goats and horses:

Meat and offal:	After IV administration:	Zero days
	After IM administration:	1 day
Milk:	Zero hours	

Pigs:

Meat and offal:	After IV administration:	Zero days
	After IM administration:	1 day

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antihaemorragics. Other systemic hemostatics.
ATCvet code: QB02BX01

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium metabisulfite (E 223)
Sodium sulfite anhydrous (E 221)
Disodium edetate
Water for injection

6.2 Major incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.
Avenida Rio de Janeiro 60 - 66
Planta 13
08016 Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10389/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 August 2019

10 DATE OF REVISION OF THE TEXT

September 2020