PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton Box with 1, 5 and 10 vials of 20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hemosilate 125 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Etamsylate 125 mg

3. PACKAGE SIZE

1x20 ml
5x20 ml
10x20 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

Pigs:
Meat and offal: After i.v. administration: Zero days
After i.m. administration: 1 day

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 14 days.
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.

14. MARKETING AUTHORISATION NUMBERS

Vm 46037/4005

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Vial of 20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hemosilate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Etamsylate 125 mg/ml

3. BATCH NUMBER

Lot. {number}

4. EXPIRY DATE

Exp. {month/year}
Once broached, use by:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Hemosilate 125 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:
Etamsylate 125 mg

Excipients:
Benzyl alcohol (E1519) 10 mg
Sodium metabisulfite (E223) 0.4 mg
Sodium sulfite anhydrous (E221) 0.3 mg

Clear and colourless solution, free from visible particles.

3. Target species

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

4. Indications for use

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

5. Contraindications

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

6. Special warnings

Special warnings:
None.

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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according 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.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
None known.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. 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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

10. 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

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 14 days.

12. Special precautions for the disposal

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 applicable nation-al collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 46037/4005

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.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Ecuphar Veterinaria S.L.U.
C/Cerdanya, 10-12 Planta 6º
08173 Sant Cugat del Vallés
Barcelona (Spain)

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Crta Camprodón, s/n, Finca La Riba
Vall de Bianya 17813 – Girona (Spain)

Local representatives and contact details to report suspected adverse reactions:

Bimeda Animal Health Limited
2, 3, 4 Airton Close, Airton Road
Tallaght, Dublin 24, Ireland
Tel: +353 (0) 1 466 790
Email: ie-pharmacovigilance@bimeda.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 07 October 2025