[Version 8.1,01/2017]

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box 1x 20 ml, 5x20 ml, 10x20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOSILATE 125 mg/ml Solution for injection (ES, IT, PT, EL, CY, MT, BE, CZ, HU, IE, RO, AT, DE, FR, NL, SI, SK, UK)
Hemosilate vet 125 mg/ml solution for injection (DK, NO, PL, SE, FI, EE)
Etamsylate

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Etamsylate 125 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1x20 ml
5x20 ml
10x20 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal:

Cattle, Sheep, Goats and Horses:
Meat and offal: After IVadministration: Zero days
After IM administration: 1 day
Milk: Zero hours

Pigs:
Meat and offal: After IVadministration: Zero days
After IM administration: 1 day

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf-life after first opening the container: 14 days
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar Veterinaria S.L.U.
Avenida Rio de Janeiro 60-66, planta 13
08016 - Barcelona (Spain)

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial containing 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOSILATE 125 mg/ml Solution for injection (ES, IT, PT, EL, CY, MT, BE, CZ, HU, IE, RO, AT, DE, FR, NL, SI, SK, UK)
Hemosilate vet 125 mg/ml solution for injection (DK, NO, PL, SE, FI, EE)
Etamsylate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Etamsylate 125 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

IV or IM.

5. WITHDRAWAL PERIODS

Withdrawal:
Cattle, Sheep, Goats and Horses:
Meat and offal: After IVadministration: Zero days
After IM administration: 1 day
Milk: Zero hours

Pigs:
Meat and offal: After IVadministration: Zero days
After IM administration: 1 day

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}
Once broached, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
HEMOSILATE 125 mg/ml Solution for injection (ES, IT, PT, EL, CY)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ecuphar Veterinaria S.L.U.
Avenida Rio de Janeiro 60-66, planta 13
08016 - 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)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOSILATE 125 mg/ml Solution for injection (ES, IT, PT, EL, CY, MT, BE, CZ, HU, IE, RO, AT, DE, FR, NL, SI, SK, UK)
Hemosilate vet 125 mg/ml solution for injection (DK, NO, PL, SE, EE, FI)
Etamsylate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

4. INDICATION(S)

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 and/or to any of the excipients.

6. ADVERSE REACTIONS

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

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 inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Cattle, Sheep, Goats and Horses:
Meat and offal: After IVadministration: Zero days
After IM administration: 1 day
Milk: Zero hours

Pigs:
Meat and offal: After IVadministration: Zero days
After IM 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 the month.
Shelf-life after first opening the container: 14 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

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.

Pregnancy and lactation:
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.

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

Overdose (symptoms, emergency procedures, antidotes):
None Known.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

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