ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hemosyvet 125 mg/ml solution for injection for cattle, sheep, goats, pigs, horses, dogs and cats.

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)	10.00 mg
Sodium metabisulfite (E223)	0.40 mg
Sodium sulfite (E221)	0.30 mg
Disodium edetate	
Water for injections	

Clear, colourless to slightly brownish 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 gynaecological 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, sulphites 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:

Undetermined frequency (cannot be estimated from the available data)	Anaphylaxis[1]

[1]: due to the presence of sulphites

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

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

Administer a dose of 5 to 12.5 mg of etamsylate/kg bodyweight, equivalent to 0.04 to 0.1 ml/kg bodyweight of the veterinary medicinal product, depending on the severity of the procedure/haemorrhage.
Treatment is normally carried out until the desired effect is achieved; 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 veterinary medicinal product should be administered at least 30 minutes before surgery.
For treatment of an ongoing haemorrhage, the veterinary medicinal 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 medicinal product.

Do not administer more than 20 ml of this veterinary medicinal product at 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

Not applicable.

3.12 Withdrawal periods

Meat and offal:
Cattle, sheep, goats, horses, pigs:
Intravenous administration: Zero days.
Intramuscular administration: 1 day.

Milk:
Cattle, sheep, goats, horses:
Intravenous and intramuscular administration: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB02BX01

4.2 Pharmacodynamics

Etamsylate is a haemostatic and angioprotective drug that stimulates platelet adhesiveness, shortening bleeding time, and rapidly and lastingly normalizes 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 haemostasis 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 haemorrhage up to 50% reaching its maximum effect between 30 minutes and 4 hours after its administration.

4.3 Pharmacokinetics

In all 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 ($t_{½}$) 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 mcg/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: 30 months.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in the original container in order to protect from light.
This medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

25 ml, type I, amber coloured glass vial, with coated bromobutyl rubber stopper and aluminium cap.
50 ml, type I, amber coloured glass vial, with coated bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Cardboard box containing 1 vial of 25 ml
Cardboard box containing 1 vial of 50 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Axience

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/352/001
EU/2/25/352/002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/10/2025

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

{MM/YYYY}

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*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hemosyvet 125 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Etamsylate 125 mg/ml

3. PACKAGE SIZE

25 ml
50 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intravenous or intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal:
Cattle, sheep, goats, horses, pigs:
Intravenous administration: Zero days.
Intramuscular administration: 1 day.

Milk:
Cattle, sheep, goats, horses:
Intravenous and intramuscular administration: Zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once broached use by: ____

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container 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

Axience

14. MARKETING AUTHORISATION NUMBERS

EU/2/25/352/001
EU/2/25/352/002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial type I (25 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hemosyvet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Etamsylate 125 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once broached use by: ____

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Hemosyvet 125 mg/ml solution for injection for cattle, sheep, goats, pigs, horses, dogs and cats.

2. 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)	10.00 mg
Sodium metabisulfite (E223)	0.40 mg
Sodium sulfite (E221)	0.30 mg

Clear, colourless to slightly brownish 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 gynaecological haemorrhages.

5. Contraindications

Do not use in cases of 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, sulphites 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 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.

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

Overdose:
None known.

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:

Undetermined frequency (cannot be estimated from the available data)	Anaphylaxis[1]

[1]: due to the presence of sulphites

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any adverse 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 contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Intravenous or intramuscular use.

Administer a dose of 5 to 12.5 mg of etamsylate/kg bodyweight, equivalent to 0.04 to 0.1 ml/kg bodyweight of the veterinary medicinal product, depending on the severity of the procedure/haemorrhage.
Treatment is normally carried out until the desired effect is achieved; 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 veterinary medicinal product should be administered at least 30 minutes before surgery.
For treatment of an ongoing haemorrhage, the veterinary medicinal 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 medicinal product.

Do not administer more than 20 ml of this veterinary medicinal product at 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

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.

10. Withdrawal periods

Meat and offal:
Cattle, sheep, goats, horses, pigs:
Intravenous administration: Zero days.
Intramuscular administration: 1 day.

Milk:
Cattle, sheep, goats, horses:
Intravenous and intramuscular administration: Zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container in order to protect from light.
This medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 28 days.

12. Special precautions for 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 national 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

EU/2/25/352/001
EU/2/25/352/002

Pack sizes:
Cardboard box containing 1 vial of 25 ml
Cardboard box containing 1 vial of 50 ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder<and contact details to report suspected adverse reactions>:
Axience
Tour Essor - 14 Rue Scandicci
93500 Pantin
France

Manufacturer responsible for batch release:
Produlab Pharma BV
Forellenweg 16
4941 SJ Raamsdonksveer
Netherlands

only in case marketing authorisation holder is also the local contact to report suspected adverse reactions: Tel: +33141832310

Local representatives and contact details to report suspected adverse reactions:

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