HEMOSILATE

Solution for Injection

DATA SHEET

INDICATIONS

- Prevention and treatment of surgical, post traumatic, obstetric and gynaecological haemorrhages.
- To be used for the prevention of bleeding prior to surgery.
- Treatment post trauma for up to 3 days in order to control ongoing bleeding.

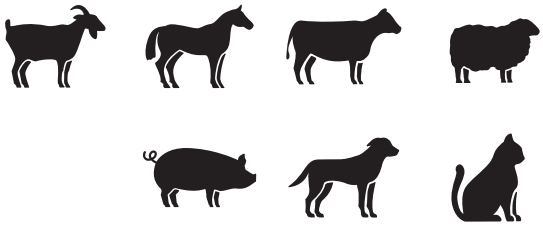
BENEFITS

- **For use in cattle, sheep, goats, pigs, horses, dogs and cats**
- **For IV or IM use**
- **Zero or short 1 day withdrawal periods**
- **Flexible use for prevention or treatment of bleeding**

LIST No	UNIT PACKAGE
1HEM001	20ml x 5

See reverse for Administration & Dosage

HEMOSILATE 125 mg/ml
Solution for Injection



PRESENTATION
Clear and colourless Solution for injection. Each ml contains Etamsylate 125 mg.

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

INDICATIONS FOR USE
Prevention and treatment of surgical, post traumatic, obstetric and gynaecological haemorrhages.

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.

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

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

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, 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 product.
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.

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.

USE DURING 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.

PHARMACODYNAMIC PROPERTIES
Etamsylate is a haemostatic 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 (PGI2) 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.

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 (T1/2) 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 (Cmax: 27; 25.8 and 10.7 µg/ml in dogs, cats and cattle respectively) approximately 1h after its administration (Tmax: 0.42; 0.54 and 1.3 h in dogs, cats and cattle respectively).

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

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

SPECIAL PRECAUTIONS FOR STORAGE
Keep the vial in the outer carton in order to protect from light.
The number of permissible stopper punctures are 10.

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.

MARKETING AUTHORISATION HOLDER
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08016 Barcelona
Spain

MARKETED IN IRELAND BY
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MARKETING AUTHORISATION NUMBER
VPA10389/004/001

LEGAL STATUS
VPO

Veterinary Practitioner Only as defined in relevant national legislation.

The complete product SPC can be found on the HPRA website.

Use Medicines Responsibly.

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.ie