Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

DECENTRALISED PROCEDURE

FINAL PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

HEMOSILATE 125 mg/ml Solution for injection

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CORREO ELECTRÓNICO
Página 1 de 8 28022 MADRID smuvaem@aemps.es TEL: 91 822 54 01
C/CAMPEZO, 1 -EDIFICIO 8
FAX: 91 822 54 43

MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0281/001/DC
Name, strength and pharmaceutical form	HEMOSILATE 125 mg/ml Solution for injection
Applicant	Ecuphar Veterinaria S.L.U. Avenida Rio de Janeiro 60-66, planta 13 08016 - Barcelona Spain
Active substance(s)	Etamsylate
ATC Vet code	QB02BX01
Target species	Cattle, sheep, goat, pig, horse, dog and cat.
Indication for use	Cattle, sheep, goat, pig, horse, dog and cat: Prevention and treatment of surgical, post traumatic, obstetric and gynecological hemorrhages.

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralisedprocedure	Day 210: 28/02/2018
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	CY, EL IT, PT and MT

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

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II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 125 mg/ml of etamsylate and benzyl alcohol, sodium metabisulphite, sodium sulphite anhydrous, EDTA disodium and water for injection as excipients

The container/closure system is a glass type I vial, closed with chlorobutyl type I stopper and flip-off aluminum cap.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

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The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is etamsylate, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practices.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

D. Control on intermediate products

N/A

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

N/A

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III. SAFETY AND RESIDUES ASSESSMENT

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

User Safety

A user safety assessment is provided according to the current guideline. It is considered that the precautions currently authorized and proposed by the applicant continue being suitable and safe for users.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the VICH GL 6 guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

Therefore, the ERA ends in Phase I, concluding that the product has an acceptable risk for the environment.

Residue Studies

No residue depletion studies were conducted with the candidate formulation on the basis that the formulation is claimed to be equivalent to that of the reference product.

MRLs

Etamsylate is included in Table 1 (Allowed substances) of the COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, in the following terms:

Active substance	Marker residue	Animal specie	MRL (µg/kg)	Target tissue
Etamsylate	Not Applicable	All food producing species	No MRL required	Not Applicable

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Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:
Meat: After iv administration: Zero days.
After im administration: 1 day

Milk: Zero days

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and Bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

As this was a generic application according to Article 13 of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, preclinical studies are not required.

IV.B Clinical Studies

As this was a generic application according to Article 13 of Directive 2001/82/EC, amended by Directive 2004/28/EC, and Bioequivalence with a reference product was demonstrated, clinical studies are not required.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the veterinary Heads of Agencies website (www.hma.eu).

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This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None

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