College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses

August 2021

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0123/001/DC
Name, strength and pharmaceutical form	EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses
Applicant	LE VET B.V Wilgenweg 7 3421 TV Oudewater The Netherlands
Active substance(s)	Trimethoprim Sulfadiazine
ATC Vetcode	QJ01EW10
Target species	Horses
Indication for use	Treatment of infections in horses caused by bacteria sensitive to the combination of trimethoprim and sulfadiazine, particularly: Respiratory tract infections, associated with *Streptococcus* spp. and *Staphylococcus aureus*; Gastrointestinal infections associated with *E. coli*; Urogenital infections associated with beta-haemolytic streptococci; Wound infections and open or drained abscesses associated with *Streptococcus* spp. and *Staphylococcus aureus.*

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

MODULE 2

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

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	3rd March 2008
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	Austria, Belgium, Germany, Denmark, Greece, Spain, Finland, France, Hungary, Ireland, Italy, Luxembourg, Norway, Poland, Portugal, Sweden, United Kingdom

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.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains Trimethoprim 66,7 mg and Sulfadiazine 333,3 mg (quantitative) and the excipients (qualitative) Chlorocresol, Anise oil, glycerol, xanthan gum, polysorbate 20 and water for injections.

The container/closure system pre–filled multi-dose polyethylene syringe with adjustable screw ring closed with polyethylene cap. Each syringe contains 45 g paste

The choice of the formulation are justified.

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

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

B. Method of Preparation of the Product

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

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is Trimethoprim and Sulfadiazine an established active substance described in the European Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products)

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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 active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

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.

The claim of a stability after reconstitution is based on the demonstration of stability for a batch broached and stored 24 monthsat 25°C.>

G. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

Shelf-life after first opening the immediate packaging: 8 weeks

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

The pharmacological and toxicological aspects of this product is/are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users / the environment .

III.A Safety Testing

Pharmacological Studies

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

Toxicological Studies

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that this product may cause sensitisation and dermatitis by contact. Therefore, avoid direct contact with the skin and eyes during application. Use suitable hand gloves.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

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

Phase I:

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. According to Table 2 from the draft guideline EMEA/CVMP/ERA/418282/2005-CONSULTATION [2], individual treatment is assumed for: "All products for horses (except ecto- or endoparasiticides)". Since SULFATRIM ORAL PASTE is no ecto- or endoparasiticide, individual treatment is assumed, according toEMEA/CVMP/ERA/418282/2005.

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

According to the decision tree given in CVMP/VICH/592/98-FINAL [1], the risk assessment in Phase I stops, since this question can be answered with Yes. We therefore conclude that a further environmental risk assessment of SULFATRIM ORAL PASTE is not necessary.

III.B Residues documentation

Withdrawal Periods

Based on the data provided above, a withdrawal period of 14 days for meat and offal in horse is justified. The product is not permitted for use in mares producing milk for human consumption

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.

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.

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

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 Heads of Vetrinary Medicines Agencies website (www.HMA.eu).

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.

Summary of change	**Section updated**	**Approval date**
Change in the name and/or the address of the marketing authorisation holder. (NL/V/0123/001/IA/001)	Module 1	16th September 2010
Extension of the shelf life of the finished product as packaged for sale (supported by real time data). (NL/V/0123/001/IB/002)	Module 3 II.G	19th September 2011
Renewal – NL as RMS. (NL/V/0123/001/R/001)	NA	7th November 2013
Change in pack size of the finished product outside the range of the currently approved pack sizes. (NL/V/0123/001/IB/003)	NA	19th August 2015
Introduction of a new manufacturer of the active substance supported by an ASMF. (NL/V/0123/001/II/004)	NA	13th January 2018
Introduction of a new Pharmacovigilance system. (NL/V/xxxx/WS/022)	NA	24th July 2019
Change in the batch size (including batch size ranges) of the finished product – Up to 10-fold compared to the originally approved batch size Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product – Minor change in the manufacturing process of an aqueous oral suspension	NA	29th July 2021

EQUIBACTIN VET. (333 mg/g +67 mg/g) Oral Paste for Horses	NL/V/0123/001/DC
LE VET B.V	DCP
	Publicly available assessment report

Change in the specification parameters and/or limits of the finished product – Deletion of a non-significant parameter Change to in-process tests or limits applied during the manufacture of the finished product – other changes (NL/V/0123/IB/006/G)		