College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Carbifusion 56 mg/ml solution for infusion for cattle and horses

Created: August 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0248/001/DC
Name, strength and pharmaceutical form	Carbifusion 56 mg/ml solution for infusion for cattle and horses
Applicant	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel The Netherlands
Active substance(s)	Sodium hydrogen carbonate
ATC Vetcode	QB05XA02
Target species	Cattle and horses
Indication for use	Adjunctive therapy in the treatment of metabolic acidosis

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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).

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	13 March 2019
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	BE, DE, FR

I. SCIENTIFIC OVERVIEW

Carbifusion is a generic application according to Article 13. The reference product is Bicarbonaat of the company Eurovet Animal Health B.V., registered in The Netherlands under REG NL 1278 since 16 January 1992. Bicarbonaat REG NL 1278 is also the product for data protection. The initial application for Bicarbonaat was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product C*arbifusion 56 mg/ml solution for infusion* is a solution for infusion containing 56 mg/ml of the active substance sodium hydrogen carbonate in water for injections.
The solution is packed in 500 ml PP bottles, closed in bromobutyl rubber stoppers and secured with aluminium caps.

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

The claimed biowaiver can be granted.

B. Method of Preparation of the Product

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

The product is manufactured using conventional manufacturing techniques. However, suitable pre-approval validation results on two production scale batches have been provided.

The tests performed during production are described.

C. Control of Starting Materials

The active substance Sodium hydrogen carbonate is an established substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

Full information has been provided in the dossier.

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.

The only excipient Water for injections is in in conformity with the Ph.Eur. requirements.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

D. Control on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. All 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 has been provided demonstrating compliance with the specification.

F. Stability

The retest period of 5 years for Sodium hydrogen carbonate when stored under the approved conditions is justified.

Stability data on the finished product have been provided in accordance with applicable the VICH guidelines. According to the stability results provided the claimed shelf life of 24 months without specific storage conditions can be granted.

G. Other Information

None.

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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.

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 and consumers.

III.A Safety Testing

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because the product applied for is identical to the reference product Bicarbonaat.

MRLs

Sodium hydrogen carbonate is listed as an Annex II substance to Commission Regulation (EU) No 37/2010, therefore no MRL is applicable.

Withdrawal Periods

Based on the data provided above, a withdrawal period of zero days for meat in cattle and horses and zero days for milk are justified.

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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.

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.

None.