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

Gujatal 100 mg/ml solution for infusion for horses

Created: 05 June 2012
Updated: January 2020

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

Dutch Registration number	REG NL 110606
EU Procedure number	NL/V/0162/001/DC
Name, strength and pharmaceutical form	Gujatal 100 mg/ml solution for infusion for horses
Applicant	Eurovet Animal Health B.V. Handelsweg 25 5531 AE BLADEL, The Netherlands
Active substance(s)	Guaifenesin
ATC Vetcode	QM03BX90
Target species	Horses
Indication for use	Induction of muscle relaxation and immobilisation, as an adjunct to balanced anaesthesia. Depending on the procedure, guaifenesin can be used in combination with different anaesthetics: - in combination with a sedative, and local anaesthetics for short procedures - in combination with appropriate general anaesthetics, for induction and/or maintenance of muscle relaxation during anaesthesia.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website: http://mri.medagencies.org/veterinary/.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23 May 2012
Concerned Member States for original procedure	DE, FR, UK

I. SCIENTIFIC OVERVIEW

Gujatal 100 mg/ml solution for infusion for horses is produced and controlled using validated methods and tests, which ensure the consistency of Gujatal 100 mg/ml solution for infusion for horses released on the market.
It can be considered that Gujatal 100 mg/ml solution for infusion for horses can be safely used in the target species; the reactions that may be expected are indicated in the SPC and that Gujatal 100 mg/ml solution for infusion for horses is safe for the user and for the environment, when used as recommended.
Suitable warnings and precautions are indicated in the SPC.
The efficacy of Gujatal 100 mg/ml solution for infusion for horses is considered as demonstrated in respect of the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

The safety and efficacy aspects of Gujatal 100 mg/ml solution for infusion for horses are based on bioequivalence with the reference product Gujatal 100 mg/ml solution for infusion, REG NL 1545. Warnings and precautions are added based on increased knowledge and the current state of science.

II. QUALITY ASPECTS

A. Composition

The application concerns Gujatal 100 mg/ml solution for infusion for horses, containing 100 mg/ml of guaifenesin.

The product contains the following excipients: glucose monohydrate, Nmethylpyrrolidone and water for injection. Hydrochloric acid and sodium hydroxide are used for pH adjustment.

The solution for infusion is packed in 500 ml polypropylene bottle fitted with a bromobutyl stopper and secured with an aluminium cap.

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

B. Method of Preparation of Gujatal 100 mg/ml solution for infusion for horses

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The product is manufactured according to a standard manufacturing process using conventional manufacturing techniques.

A process validation report has been included. The manufacturing process is completely validated.

The process validation data show that the formulation and manufacturing process of the product Guaifenesin infusion is fully under control to produce a product that meets the pre-set specifications and that no trends are present.

The tests performed during production are described. Adequate in-process specifications are provided.

C. Control of Starting Materials

The active substance is guaifenesin, an established active substance described in the European 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.

The excipients are in conformity with the requirements of their Ph.Eur. monographs.

The polpypropylene bottles and stoppers are in conformity with the Ph.Eur. requirements.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The specification is 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 sites have been provided demonstrating compliance with the specification.

G. Stability

The Certificates of Suitability from both active substance manufacturers confirm the retest period 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 the claimed shelf life of 48 months without any special storage conditions.

H. Genetically Modified Organisms

None

J. Other Information

None

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been accepted based on exemption a) and d) of section 7.1 of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products, EMA/CVMP/016/00-Rev.-2, results of toxicological, pharmacological and residue tests are not required.

Warnings and precautions as listed on the product literature are based on those of the reference product but supplemented using provided safety studies, increased knowledge and the current state of science and are adequate to ensure safety of Gujatal 100 mg/ml solution for infusion for horses to users / the environment / consumers.

III.A Safety Testing

Pharmacological Studies

For this generic procedure, the applicant refers to the reference product, for which it was show that guaifenesin is a centrally acting muscle relaxant. Guaifenesin selectively blocks nerve impulse transmission in the binding neurons of the spinal cord, brainstem and subcortical regions of the brain. The onset of action is within minutes. The effect of guaifenesin lasts approximately 820 minutes. The animals stand again within 45 minutes after administration.

Toxicological Studies

The applicant refers to the reference product for this generic procedure, from which the SPC warnings have been derived. These are supplemented using increased knowledge and the current state of science.

The applicant refers to the reference product for this (auto) generic procedure, Gujatal, 100mg/ml, solution for infusion, REG NL 1545, from which the SPC warnings have been derived.

User Safety

The applicant refers to the reference product for this generic procedure.

Additionally the applicant has provided a brief user safety assessment. Combined with increased knowledge and the current state of science, warnings and precautions are added to the product literature ensuring safety to users of Gujatal 100 mg/ml solution for infusion for horses.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because for this generic procedure, the applicant refers to the reference product.

Gujatal 100 mg/ml solution for infusion for horses is not to be used in horses intended for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with the reference product, Gujatal 100 mg/ml, solution for infusion, REG NL 1545, has been accepted based on exemption a) and d) of section 7.1 of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products, EMA/CVMP/016/00-Rev.-2, efficacy studies are not required. The efficacy claims for this product are essentially equivalent to those of the reference product.

Tolerance in the Target Species of Animals

The applicant refers to the reference product for this generic procedure.

Additionally, based on increased knowledge and the current state of science, warnings and precautions are added to the product literature ensuring safety to the target animals.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when Gujatal 100 mg/ml solution for infusion for horses 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 Gujatal 100 mg/ml solution for infusion for horses 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 Veterinary 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
Changes to an existing pharmacovigilance system as described in the DDPS, change in QPPV (NL/V/xxxx/IA/006/G)	N/A	6 March 2013
Submission of an updated Ph. Eur. Certificate of suitability from an already approved manufacturer Deletion of a Ph. Eur. Certificate of suitability (NL/V/0162/IA/002/G)	N/A	9 November 2016
Renewal (NL/V/0162/001/R/001)	N/A	26 May 2017
Submission of an updated Ph. Eur. Certificate of suitability from an already approved manufacturer (NL/V/0162/001/IA/003)	N/A	13 November 2017
Changes to an existing pharmacovigilance system as described in the DDPS, change in QPPV (NL/V/xxxx/IA/033/G)	N/A	11 January 2019
Submission of an updated Ph. Eur. Certificate of suitability from an already approved manufacturer (NL/V/0162/001/IA/005)	N/A	28 September 2019