College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vomend 5 mg/ml, solution for injection for dogs and cats

NL/V/0145/001/DC

March 2014

MODULE 1

PRODUCT SUMMARY

Dutch Registration number	REG NL 106887
EU Procedure number	NL/V/0145/001/DC
Name, strength and pharmaceutical form	Vomend, 5 mg/ml, solution for injection.
Applicant	Eurovet Animal Health B.V. Handelsweg 25 5531AE, Bladel the Netherlands
Active substance(s)	Metoclopramide hydrochloride
ATC Vetcode	QA03FA01
Target species	Dogs, cats
Indication for use	Symptomatic treatment of vomiting and reduced gastro-intestinal motility associated with gastritis, pyloric spasm, chronic nephritis and digestive intolerance to some drugs.

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	15 November 2010
Concerned Member States for original procedure	AT, BE, DE, ES, FI, FR, IT, LU, PT, SE, UK.

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.

The safety and efficacy aspects of Vomend, 5 mg/ml, solution for injection are based on demonstrated bioequivalence with the reference product (Primperid inj., REG NL 1947). 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 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. Composition

The product contains metoclopramide hydrochloride monohydrate, equivalent to 4.457 mg/ml metoclopramide, and excipients benzyl acohol, sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

The container/closure system comprises multidose uncoloured glass vials type 1 (Ph.Eur.) closed by bromobutyl rubber stoppers type 1 (Ph.Eur.) and aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and presence of preservative are justified.

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

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 metoclopramide hydrochloride, 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.

A CEP was supplied for the active substance manufacturer.

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 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.

G. 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 28-day stability after broaching has been justified, as well as the storage conditions of the opened product.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product (Primperid inj., REG NL 1947) has been demonstrated, results results of pharmacological tests were not required. These aspects are identical to the reference product.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product (Primperid inj., REG NL 1947) has been demonstrated, results of toxicological tests are not required. The toxicological aspects of this product are identical to the reference product.

User Safety

As this is a generic application according to Article 13, and bioequivalence with a reference product (Primperid inj., REG NL 1947) has been demonstrated, results of user safety tests are not required.

Additional user safety statements have been added, based on increased knowledge and the current state of science.Warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users.

Ecotoxicity

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

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, tolerance studies are not required. The tolerance claims for this product are equivalent to those of the reference product (Primperid inj., REG NL 1947).

Bibliographical data have also been provided which show that the addition of 1.8% benzyl alcohol is safe with respect to local and systemic tolerance of injectable formulations.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

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 (Primperid inj., REG NL 1947).

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.