Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vetemex 10 mg/ml solution for injection for dogs and cats (CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LV, PL, PT, RO, SI, SK, UK(NI))
Vetemex vet 10 mg/ml solution for injection for dogs and cats (AT, BE, DK, FI, NL, SE)

Date: 06 March 2023

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0304/001/MR
Name, strength and pharmaceutical form	Vetemex 10mg/ml solution for injection for dogs and cats
Applicant	CP-Pharma Handelsgesellschaft mbH
Active substance(s)	Maropitant
ATC Vetcode	QA04AD90
Target species	Dogs and cats
Indication for use	Dogs For the treatment and prevention of nausea induced by chemotherapy. For the prevention of vomiting except that induced by motion sickness. For the treatment of vomiting, in combination with other supportive measures. For the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the μ-opiate receptor agonist morphine. Cats For the prevention of vomiting and the reduction of nausea, except that induced by motion sickness. For the treatment of vomiting, in combination with other supportive measures.

MODULE 2

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

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 mutual recognition procedure	19 December 2018
Date product first authorised in the Reference Member State (MRP only)	11 April 2018
Concerned Member States for original procedure	AT; BE; CZ; DK; ES; FI; FR; HU; IE; IT; NL; PL; PT; SE; SK; UK
Concerned Member States for subsequent recognition procedure	EE; EL; HR; LT;LV; RO; SI

I. SCIENTIFIC OVERVIEW

The product has been developed as a generic of Cerenia 10 mg/ml, solution for injection for dogs and cats. The reference product is marketed by Zoetis Belgium and has been granted a marketing authorization in a centralized European procedure in 2006.

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 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 Maropitant as the active substance and the following excipients: Benzyl alcohol, Betadex sulfobutyl ether sodium, Citric acid anhydrous, Sodium hydroxide and Water for injections.

The container/closure system is an amber glass type I vial closed with a coated bromobutyl rubber stopper and aluminium cap in a cardboard box.

The choice of the formulation is justified.

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

The particulars of the containers and controls performed are provided and conform to the regulation.

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.

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 Maropitant, 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.

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

Not applicable.

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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required, other than to support the user risk assessment.

The differences in quality and quantity of the excipients between test and reference product do not represent a hazard to the user. Therefore, safety aspects of this product are equivalent to those of the reference product.

User safety

Warnings and precautions as listed on the product literature are adequate to ensure user safety of the product. Differences of the safety phrases between both products are due to the content of benzyl alcohol and due to an adaption of the wording on the ABCD format according to the user safety guideline.

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 only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1) of Directive 2001/82/EC as amended, 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

Pharmacology

Both, the candidate (Vetemex, CP Pharma) and the reference product (Cerenia, Zoetis Belgium) are aqueous solutions for intravenous and subcutaneous use, indicated for the treatment and prevention of nausea and vomiting in cats and dogs.

The candidate product Vetemex contains the same concentration of the active substance as the reference product Cerenia.
However, the reference and the generic veterinary medicinal product differ in quality and quantity of the excipients.
Since the applicant demonstrated that differences in the excipients and/or their concentrations will have no influence on the rate and extent of absorption of the active substance, bioequivalence of the reference product Cerenia and the candidate product Vetemex can be concluded.

As the application is a generic application and bioequivalence of candidate and reference is accepted, the applicant is not required to provided studies on pharmacology.

Tolerance in the Target Species of Animals

As the application is a generic application and bioequivalence of candidate and reference is accepted, the applicant is not required to provide results of target animal tolerance studies.

IV.B Clinical Studies

Laboratory Trials

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC and bioequivalence of the candidate and the authorized reference product is concluded, data of laboratory trials are not required.

Field Trials

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC and bioequivalence of the candidate and the authorized reference product is concluded, data of the field trials 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 in the Union Product Database (UPD).

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.

Quality changes

Summary of change (Application number)	**Section updated in Module 3**	**Approval date**
Change in the (invented) name of the medicinal product for Nationally Authorised Products (DE/V/0304/001/IB/002)	N/A	09.05.2019

Other changes

Summary of change (Application number)	**Section updated in Module 3**	**Approval date**
G.I.18. One-off alignment of the product information with version 9.0 of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive	N/A	29.07.2022

2001/82/EC or Regulation (EC) No 726/2004 (DE/V/0304/001/A/006)		