Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Vominil 10 mg/ml Solution for Injection for Dogs and Cats

Date Created: December 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Vominil 10 mg/ml Solution for Injection for Dogs and Cats
Applicant	VetViva Richter GmbH Durisolstrasse 14 4600 Wels Austria
Active substance	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) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

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 conclusion of the procedure	29/9/2023

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, any reactions observed are indicated in the SPC.[1] 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 [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

The quality / safety / efficacy aspects of this product are identical to Cerenia 10 mg/ml Solution for Injection for Dogs and Cats. The initial application for Cerenia was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains maropitant and the excipients n-Butanol, dexolve (SBECD) and water for injections.

The container/closure system consists of amber Type I glass vials closed with chlorobutyl stoppers and an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the 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.

II.B. Description of the Manufacturing Method

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of: dissolving, filtering and sterilising.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substance is maropitant, an established active substance described in the ASMF. 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 excipient, with the exception of n-butanol, are described in Ph. Eur. N-butanol is described in the USP monograph.

The packaging materials comply with Ph. Eur.

II.C.4. Substances of Biological Origin

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

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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. Control tests on the finished product are those for: appearance, colour, clarity, density, visible particles, identity, assay of maropitant and n-butanol, impurities, sterility and pH.

II.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

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 28 days
Do not freeze.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required due to the legal basis of the application.

Toxicological Studies

Not required.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:,

This product may cause skin sensitisation. People with known hypersensitivity to maropitant should administer the veterinary medicinal product with caution.
Wash the exposed skin immediately after exposure with large amounts of water.
If you develop symptoms such as a rash after accidental exposure, seek medical advice and show the physician this warning.
This veterinary medicinal product may be irritant to the eyes. Avoid eye contact.
In case of accidental contact of the product with eyes rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.
Maropitant is a neurokinin-1 (NK1) receptor antagonist that acts in the central nervous system. Accidental self-injection or ingestion may result in nausea, dizziness and somnolence. Care should be taken to avoid accidental self-injection. In case of accidental oral intake or self-injection seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

Not required due to the legal basis of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the product is favourable.

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)