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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Telmitraxx 4 mg/ml Oral Solution for Cats

Date Created: August 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Telmitraxx 4 mg/ml Oral Solution
Applicant	Alfasan Nederland B.V. Kuipersweg 9 3449 JA Woerden The Netherlands
Active substance	Telmisartan
ATC Vetcode	QC09CA07
Target species	Cats
Indication for use	Reduction of proteinuria associated with chronic kidney disease (CKD).

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	21/07/2023

I. SCIENTIFIC OVERVIEW

Th application for Telmitraxx 4 mg/ml oral solution for cats is a generic product, submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended. The reference product is Semintra 4mg/ml oral solution for cats, which has been marketed in the UK since February 2013

This product is indicated for use in cats as an aqueous solution for the reduction of proteinuria associated with chronic kidney disease (CKD) and for the treatment of systemic hypertension in cats.

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.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains 4mg/ml of telmisartan as active substance and the excipients 0.1 mg/ml of benzalkonium chloride and 1 mg/ml of disodium edetate as preservatives. Other ingredients are maltitol as a flavouring agent,

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

hydroxyethyl cellulose as a thickening agent with sodium hydroxide and dilute hydrochloric acid used for pH adjustment.

The container/closure system consists of a white high-density polyethylene (HDPE) bottles closed with a polypropylene (PP) closure incorporating a low-density polyethylene (LDPE) plug. 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

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of dissolution of the components followed by filtration.

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 telmisartan an established active substance described in the European Pharmacopoeia and sourced from a single supplier in accordance with a valid certificate of suitability (CEP). 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.

The excipients are benzalkonium chloride, disodium edetate, hydroxyethylcellulose, sodium hydroxide (for pH adjustment)' hydrochloric acid, diluted (for pH adjustment). Maltitol, and purified water. All excipients are the subject of Ph. Eur. monographs,

The finished product is presented in 30, 60, 100 or 200 ml white high-density polyethylene (HDPE) bottles closed with a polypropylene (PP) closure incorporating a low density polyethylene (LDPE) plug.

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, pH, Density, Volume, Clarity and Colour.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

G. Other Information

- Store below 30°C
- Store in the original container in order to protect from light.
- Shelf life of the veterinary medicinal product as packaged for sale: 21 months.
- Shelf life after first opening the immediate packaging: 6 months.
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III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Due to the legal base of the application, pharmacological data were not provided expect in support of the User Risk Assessment.

Toxicological Studies

Due to the legal base of the application Toxicological data were not provided expect in support of the User Risk Assessment.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that excipients are not likely to cause toxic effects at the levels present in the pharmaceutical form. With regards to the active acute oral toxicity was low in rats and dogs, with no adverse effects being noted at doses of up to 2000 mg/kg bw. The principal toxicological target organs were the kidney and the gastrointestinal tract. The mechanism of the gastrointestinal toxicity (ulcers and erosions) is not known. A NOEL was not available from these studies. No reproductive or teratogenic toxic effects were reported in lab studies. However, telmisartan is contraindicated during pregnancy in human medicine due to increased risk of foetal and neonatal toxicity and death. Telmisartan is not considered to be genotoxic or carcinogenic.

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 adverse effects, such as headache, dizziness or hypotension. Avoid oral ingestion by children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- This product may cause eye-irritation. Avoid eye contact. In case of accidental eye contact, rinse eyes with water.
- Pregnant women should take special care to avoid contact with the veterinary medicinal product because substances acting on the RAAS, such as Angiotensin Receptor Blockers (ARBs) and ACE inhibitors (ACEis), have been found to affect the unborn child during pregnancy in humans.
- Telmisartan may cause allergic reactions. People with hypersensitivity to telmisartan or other sartans/ARBs should avoid contact with the veterinary medicinal product.
- 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

A bioequivalence study confirmed that the Semintra 4 mg/ml and 10 mg/ml strength formulations were bioequivalent. Therefore, the use of the lower Semintra 4 mg/ml strength in the pivotal EU study investigating the safety and efficacy of telmisartan for the treatment of systemic hypertension in cats was accepted by the CVMP (EMA/186850/2018) in support of the authorisation of Semintra 10 mg/ml. Therefore, pharmacological data was 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 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.

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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.

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