College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Telmitraxx 4 mg/ml oral solution for cats

NL/V/0386/001/DC

PRODUCT SUMMARY

EU procedure number	NL/V/0386/001/DC
Name, strength and pharmaceutical form	Telmitraxx 4 mg/ml oral solution for cats
Applicant	Alfasan Nederland BV Kuipersweg 9 3449 JA Woerden The Netherlands
Active substance(s)	Telmisartan
ATC vetcode	QC09CA07
Target species	Cats
Indication for use	Reduction of proteinuria associated with chronic kidney disease (CKD)

PRODUCT INFORMATION

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).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	Semintra 4 mg/ml oral solution for cats
Marketing authorisation holder	Boehringer Ingelheim Vetmedica GmbH
MS where the RP is or has been authorised	EU
Marketing authorisation number EU procedure number	EU/2/12/146/001-002
Date of authorisation	13th of February 2013
Date of completion of the original decentralised procedure	31st of May 2023
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SE, SI, SK, UK(NI)
Concerned Member States for subsequent recognition procedure	-
Withdrawn CMS during original decentralised procedure	NA

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP 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 VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

Telmitraxx 4 mg/ml Oral solution for cats is an oral solution containing 4 mg/ml of the active substance Telmisartan. Excipients included are benzalkonium chloride solution, maltitol, Hydroxyethyl cellulose, disodium edetate, purified water, sodium hydroxide and hydrochloric acid.

The oral solution is packed in white HDPE bottles provided with an low-density polyethylene (LDPE) plug-in adapter, and is closed with a polypropylene (PP) cap. A bottle contains 30 ml (in a 30 ml bottle), 60 ml (in a 60 ml bottle), 90 ml (in a 100 ml bottle) and 200 ml (in a 200 ml bottle) oral solution. One measuring 3 mL syringe is provided. This syringe fits onto the bottle and has a ml scale.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. The choice of the formulation and the presence of a preservative (benzalkonium chloride solution) are adequately justified.

The applicant concluded that the need for an in vivo bioequivalence study can be waived. This waive is accepted.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the product of a 50 L and 90 L batch size have been presented in accordance with the relevant European guidelines. For the largest batch size of 900 L a process validation protocol has been presented that meets the requirements of the Annex I to the EMA Guideline on Process Validation for finished products. The applicant commits to validate the first two commercial batches of the largest batch size. This is acceptable.

C. Production and control of starting materials

The active substance is Telmisartan, 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 tests carried out on isolated intermediates during the manufacturing process

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. A test for uniformity and accuracy of doses has been added to the specification of the syringe and, hence, a test in the specification of the finished product is not necessary. The lack of a test for viscosity in the specification of the finished product has been adequately justified as viscosity does not change during the proposed shelf life.

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 tests

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 VICH guidelines. According to the stability results provided the claimed shelf life of 21 months with storage precaution: ‘Store below 30°C. Store in the original container in order to protect from light’ can be granted.

According to the in-use stability results provided, the claimed in-use shelf-life of 6 months can be granted.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of safety and residues tests are not required.

User safety

Being a generic procedure the applicant refers to the reference product for information on this section. Additionally the applicant has provided a user safety risk assessment in compliance

with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

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 VMP will only be used in non-food animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. 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 VMP.

None