College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Cartaxx 50 mg/ml solution for injection for dogs and cats

PRODUCT SUMMARY

EU procedure number	NL/V/0408/001
Name, strength and pharmaceutical form	Cartaxx 50 mg/ml solution for injection for dogs and cats
Applicant	Alfasan Nederland BV Kuipersweg 9 3449 JA Woerden The Netherlands
Active substance(s)	Carprofen
ATC vetcode	QM01AE91
Target species	Dog and cat
Indication for use	Dog: for the control of post-operative pain and inflammation following orthopaedic and soft tissue (including intra-ocular) surgery. Cat: for the control of post-operative pain following surgery.

Product name	NL/V/0408/001
Applicant	DCP
Publicly available assessment report	

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)	Rimadyl injectievloeistof, 50 mg/ml voor honden en katten
Marketing authorisation holder	Zoetis B.V.
MS where the RP is or has been authorised	NL
Marketing authorisation number EU procedure number	REG NL 10101
Date of authorisation	January 2004
Date of completion of the original decentralised procedure	20 December 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Withdrawn CMS during original decentralised procedure	

*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

The VMP contains Carprofen (50 mg/mL). The excipients are Benzyl alcohol, Sodium hydroxide, Glycocholic acid, Lecithin, L-Arginine, Hydrochloric acid, dilute (for pH control), Sodium hydroxide (for pH control) and Water for injections.

The container/closure system is a sterile and multi-dose container: a 10, 20 mL and 50 mL sized, colourless, type I glass vial, which is closed by a grey type I rubber stopper and sealed by an aluminium cap.

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

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

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 two batches of the lowest batch size of the drug product have been presented in accordance with the relevant European guidelines. A validation protocol as per Annex I to the EMA Guideline on Process validation has been submitted for the larger batch size together with a commitment to validate the first two commercial batches of the largest batch size.

The VMP is manufactured including standard manufacturing techniques. The proposed non-sterilising filter is accepted.

C. Production and control of starting materials

The active substance is Carprofen, an active substance described in the European Veterinary Pharmacopoeia, the USP and the British Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification presented by the DPM is considered adequate to control the quality of the API.

The excipients are in conformity with the Ph.Eur. requirements, except for Lecithin (USP) and Glycocholic acid (in-house). The specifications of the excipients are acceptable.

The proposed container closure system is well justified. The specification of the container’s components is acceptable.

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

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 VMP.

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 have been provided on two batches of the proposed veterinary medicinal product for 18 months under long-term and intermediate conditions, and 6 months under accelerated stability conditions. Also the stability results of the inverted product have been provided up to six months under long-term stability condition. All results are within the proposed specification limits. The proposed shelf-life of 30 months is acceptable. The proposed storage condition is acceptable as the product has been found to be photosensitive.

The claim of a 28 days in-use stability after first opening is based on the demonstration of stability for two batches broached and stored 28 days at +25°C at the beginning of shelf life for up to six months. The applicant commits to repeat the in-use stability test when the end of the shelf life is approaching, as per NfG on in-use stability testing of veterinary medicinal products. The preservative effect of Benzyl alcohol has been demonstrated up to 28 days.

G. Other information

None

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 tests are not required.

The safety aspects of this VMP is/are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the VMP to users and the environment.

A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

The same user safety warnings approved for the reference product were proposed to be applied to the VMP.

Additionally, as hypersensitivity reactions due to the presence of active substance carprofen or excipient benzyl alcohol cannot be excluded, the user should be warned and the hazard should be specified.

A risk characterization for accidental self-injection was performed. Gastrointestinal effects, such as nausea, diarrhea are more common side effects, but also peptic ulceration and gastrointestinal bleeding have been reported in humans.
Although it can be questioned whether serious adverse effects would occur after single exposure, it is agreed that adverse effects cannot be fully excluded after accidental self-injection. Therefore, it is justified to have warnings in place for accidental self-injection.

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