College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

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

2nd of December 2013:

MODULE 1

PRODUCT SUMMARY

Dutch Registration number	REG NL 112210
EU Procedure number	NL/V/0175/001/DC
Name, strength and pharmaceutical form	Carprofelican 50 mg/ml solution for injection for dogs and cats
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater The Netherlands
Active substance(s)	Carprofen
ATC Vetcode	QM01AE91
Target species	Dogs and cats.
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.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website: http://mri.medagencies.org/veterinary/.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	NL/V/0175/001/DC: Application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	16th of May 2013.
Concerned Member States for original procedure	AT, BE, CZ, DK, ES, EE, FI, FR, EL, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, SK, SE, UK.

I. SCIENTIFIC OVERVIEW

Carprofelican 50 mg/ml solution for injection for dogs and cats is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
The product can be safely used in the target species; possible adverse reactions are indicated in the SPC.
Carprofelican 50 mg/ml solution for injection for dogs and cats is considered safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

The safety and efficacy aspects of Carprofelican 50 mg/ml solution for injection for dogs and cats are based on bioequivalence with the reference product Rimadyl solution for injection, REG NL 10101.
Warnings statements and precautions are adopted from the reference product.
Additional statements have been added, based on increased knowledge and the current state of science. Adverse events and contraindications are indicated in the SPC.

II. QUALITY ASPECTS

A. Composition

The product contains 50 mg carprofen and the following excipients: L-arginine, glycocholic acid, lecithin, benzyl alcohol and water for injection. Hydrochloric acid and sodium hydroxide are used for pH adjustment.

The product is packed in amber type I glass bottles of 50 ml, fitted with bromobutyl rubber stoppers and aluminium caps. The glass vials and stoppers are in conformity with the Ph.Eur. requirements

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

B. Method of Preparation of the Product

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

The product is manufactured using conventional manufacturing techniques. The tests performed during production are described.

Suitable process validation has been conducted on two in initial production scale batches. Validation of the manufacturing process will be fulfilled on the first two larger post-marketing batches.

C. Control of Starting Materials

The active substance is carprofen, an established active substance described in the European/British Veterinary 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.

The excipients are in conformity with compendial or in-house requirements

The glass vials and stoppers are in conformity with the Ph.Eur. requirements

The TSE declaration concerning glycocholic acid has been provided. No other excipients are 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, confirming the retest period 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.

The claim of 28 days stability after broaching has been justified.

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

User Safety

The applicant has provided a brief user safety assessment. Combined with increased knowledge and the current state of science, warning statements and precautions have been added to the product literature, ensuring safety to users of Carprofelican 50 mg/ml solution for injection for dogs and cats

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The

efficacy claims for this product are essentially equivalent to those of the reference product.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological and pharmacological tests are not required.

However, an extensive overview of tolerance data presented in public literature has been provided by the applicant. Additionally, based on increased knowledge and the current state of science, warning statements and precautions have been added to the product literature ensuring safety to the target animals.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when Carprofelican 50 mg/ml solution for injection for dogs and cats 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.