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College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Carporal Vet 40 mg tablets for dogs
Carporal Vet 160 mg tablets for dogs

Created: December 2019

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0191/001-002/DC
Name, strength and pharmaceutical form	Carporal Vet 40 mg tablets for dogs Carporal Vet 160 mg tablets for dogs
Applicant	Le Vet. Beheer B.V. Wilgenweg 7 3421 TV Oudewater The Nederlands
Active substance(s)	Carprofen
ATC Vetcode	QM01AE91
Target species	Dogs
Indication for use	Reduction of inflammation and pain caused by musculoskeletal disorders and degenerative joint disease. As a follow up to parenteral analgesia in the management of post-operative pain.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Hybrid application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	20 May 2015
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, CY, CZ, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NO, PL, PT, RO, SE, SI, SK, UK

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; the slight reactions observed are indicated in the SPC.
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 of the product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

Carporal Vet is a hybrid application. The reference product is Rimadyl 50 mg tabletten (REG NL 8935, authorization holder Pfizer Animal Health B.V). In the Netherlands, the reference product was authorized on 6 April 1998, but was withdrawn in 2008 and replaced by Rimadyl 50 mg smakelijke tabletten. The earliest authorization for Rimadyl originates from the UK (17 March 1993).

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The tablets contain 40 mg and 160 mg Carprofen and the following core excipients:

Lactose monohydrate , Cellulose, Sodium starch glycolate (type A), Maize starch, Pregelatinized maize starch, Colloidal anhydrous silica, Calcium behenate, Yeast (deactivated) and Artificial beef flavour.

The tablet is cross scored and meant to be broken in halves or quarters.

The products are packed in PA/Al/PVC-Al blisters.

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

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A bioequivalence study has been done with 40 mg tablets against Rimadyl 50 mg tablets.

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 granulate is validated on 25% of the maximal production scale. Based on the common granulate batch size, the proposed tablet batch sizes are acceptable. The tests performed during production are described.

C. Control of Starting Materials

The active substance Carprofen for veterinary use is an established active substance described in the European Pharmacopoeia.

The ASMF procedure has been employed and no concerns were raised.

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.

All excipients are in conformity with the Ph.Eur. requirements.

The packaging is conformity with the Ph Eur and EU Food Directive.

There are no substances of biological origin within 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. All 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 with the ASMF and are in accordance with applicable VICH guidelines, confirming the retest period of the active substance when stored under the approved conditions.

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Stability data on the finished product have been provided in accordance with applicable VICH guidelines. According to the stability results provided he claimed shelf life of 36 months can be granted.

G. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years. A divided tablet should be used within 3 days.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The dossier is based on Article 13(3), a hybrid application. The reference product is Rimadyl 50 mg tabletten (REG NL 8935, authorization holder Pfizer Animal Health B.V). An *in vivo* bioequivalence study has been performed with the German Rimadyl 50 mg tabletten (Pfizer GmBH, Zul. Nr: 400064.01.00, authorized since 26 November 2002) as reference product. In the randomised cross-over trial 20 Beagles (males and females, 3 years old) received a single administration of 4 mg/kg body weight carprofen using Rimadyl 50 mg tabletten and Carporal Vet 40 mg Tabletten with a suitable wash out period in between. Bioequivalence of Carporal Vet 40 mg Tabletten with the reference article Rimadyl 50 mg Tabletten was demonstrated on the basis of the plasma concentrations of the parent compound carprofen since the 90% confidence intervals of the ratios of Cmax, AUC 0-t and AUC 0-inf were within the range of 0.8-1.25. As the bioequivalence study showed that the product is a generic of the reference product, the applicant was not required to provide results of the safety or preclinical and clinical trials.

Toxicological Studies

The applicant has provided a bioequivalence study which show that the product is a generic of Rimadyl 50 mg tabletten, therefore the applicant is not required to provide toxicological studies according to article 13 of Directive 2001/82/EC.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are: *"In the event of accidental ingestion of the tablets, seek medical advice and show the package leaflet or the label to the physician. Wash hands after handling the product."* These warnings are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. As the product is used only to treat individual non-food animals, there is no need to perform a Phase II assessment.

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IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a hybrid 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 equivalent to those of the reference product.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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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 Heads of Veterinary Medicines Agencies website (www.HMA.eu).

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 product.

Summary of change	**Section updated**	**Approval date**
Addition of secondary packaging site and batch release site (NL/V/0191/IA/002/G).	N/A	30 August 2015
Introduction of a new Pharmacovigilance system (Dechra Pharmaceuticals PLC DDPS) which has been assessed by the relevant national competent authority/EMA for another product of the same MAH (.NL/V/xxxx/WS/021)	N/A	12 June 2016
Renewal (NL/V/0191/001/R/001)	N/A	Pending

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