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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

CARPRODYL QUADRI 120 MG CHEWABLE TABLETS FOR DOGS

DATE : 25/01/2017

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0172/002/DC
Name, strength and pharmaceutical form	Carprodyl Quadri 120 mg Chewable Tablets For Dogs
Applicant	CEVA SANTE ANIMALE – 200 AVENUE DE MAYENNE – ZI DES TOUCHES – 53000 LAVAL - FRANCE
Active substance(s)	Carprofen
ATC Vetcode	QM01AE91
Target species	Dogs
Indication for use	In the dog: Reduction of inflammation and pain caused by musculo-skeletal 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 website http://www.anmv.anses.fr/

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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 completion of the original decentralised procedure	30/09/2009
Concerned Member States for original procedure	AT, BE, DE, DK, EL, ES, FI, HU, IT, NL, PL, PT, SE, 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.

II. QUALITY ASPECTS

A. Composition

The product contains 120 mg carprofen and pig liver flavour, yeast, croscarmellose sodium, copovidone, magnesium stearate, anhydrous colloidal silica, microcrystalline cellulose and lactose monohydrate.
The product is presented in PVDC-PVC/Aluminium heat sealed blisters with 6 tablets / blister. The particulars of the containers and controls performed are provided and conform to the regulation.

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.

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The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches has been performed post-authorisation.

C. Control of Starting Materials

The active substance is carprofen, an established active substance. 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control on intermediate products

Not applicable.

F. 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.

G. Stability

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 European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.
An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

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Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

Toxicological Studies

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

The toxicological aspects of this product are identical to the reference product.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that no additional risks are expected as compared to the reference product
.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

The applicant has conducted one comparative dissolution study with the product Carprodyl Quadri 120 mg and the reference product.
Bioequivalence between the product Carprodyl Quadri 120 mg and the reference product is considered demonstrated.

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Tolerance in the Target Species of Animals

The applicant has not provided a tolerance study which is acceptable because the tested product and the reference product are bioequivalent, and the safety of the excipients of the tested formulation is acknowledged.

Furthermore, a palatability study showed that the palatability of the tested product is similar to the one the reference product.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, clinical 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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