Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dolocarp flavour 20 mg
Dolocarp flavour 50mg
Dolocarp flavour 100mg

Date: 20 April 2016

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0142/001-003/DC
Name, strength and pharmaceutical form	Dolocarp flavour 20 mg Dolocarp flavour 50mg Dolocarp flavour 100mg chewable tablet
Applicant	aniMedica GmbH Im Südfeld 9, D-48308 Senden
Active substance(s)	Carprofen
ATC Vetcode	QM 01 AE 91
Target species	Dog
Indication for use	Reduction of inflammation and pain caused by acute and chronic musculoskeletal disorders (e.g. osteoarthritis). 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 Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 32 of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	28.09.2011
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, BE, EL, ES, FI, FR, HU, IE, IT, NL, PL, PT, RO, SI, 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; when used as recommended. Adverse reactions are adequately described in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals 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 Carprofen (20/50/100 mg/tablet) as the active substance and the following excipients: maize starch, lactose monohydrate, sucrose, wheat germ hydrolysate powder, magnesium stearate, calcium hydrogen phosphate anhydrous,

soy protein hydrolysate powder, povidone, liver flavour liquid, silica colloidal anhydrous, special dry flavour vegetarian, purified water.

The container/closure system consists of a white bottle made of high-density polyethylene with a childproof seal in a cardboard box. The product is closed with a white polypropylene cap with or without a desiccant.

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

C. Control of Starting Materials

The active substance is carprofen, 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.

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.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13.1, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required.

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

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users and the environment.

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)

As this is a generic application according to Article 13.1, 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.

IV.A Pre-Clinical Studies (pharmaceuticals only)

Pharmacology (if relevant – or delete)

The application is made in accordance with Article 13.1 of the Directive 2001/82/EC as amended by Directive 2004/28/EC.

The global reference veterinary medicinal products is Rimadyl tablet 20 mg authorised in Germany in 1997. The reference veterinary medicinal products authorised in Germany in 2002 and belonging to the global marketing authorisation (Article 5.1 second subparagraph of Directive 2001/82/EC as amended) are Rimadyl chewable tablets 20 mg, 50 mg and 100 mg. Rimadyl chewable tablets 100 mg was used as reference veterinary medicinal product in the pivotal bioequivalence study.

This study successfully demonstrated the bioequivalence between Dolocarp flavour 100 mg chewable tablet for dogs and Rimadyl chewable tablets 100 mg according to the requirements of the relevant Guideline EMEA/CVMP/016/00-corr-FINAL. The applicant presented *in vitro* equivalence data for the additional strengths Dolocarp flavour 20 mg and 50 mg. The dissolution profiles of both strengths show a similar dissolution to the 100 mg strength. Therefore, the results of the bioequivalence study can be extrapolated to Dolocarp flavour 20 mg and 50 mg.

On the basis of being generics of a reference medicinal product, no further information is required as it has already been presented for the reference product.

Tolerance in the Target Species of Animals

The application is made in accordance with Article 13.1 of Directive 2001/82/EC as amended by Directive 2004/28/EC.

Based on information provided in support of this application it is accepted that the test product Dolocarp flavour 100 mg is bioequivalent to the reference product and the results of the bioequivalence study can be extrapolated to Dolocarp flavour 20 mg and 50 mg.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

A palatability study has been performed. The results support the information given in section 4.9 of the SPC and in the product literature: “Most dogs will voluntarily ingest Dolocarp chewable tablets.”

IV.B Clinical Studies

The application is made in accordance with Article 13.1 of Directive 2001/82/EC as amended by Directive 2004/28/EC.

Based on information provided in support of this application it is accepted that the test product Dolocarp flavour 100 mg is bioequivalent to the reference product and the results of the bioequivalence study can be extrapolated to Dolocarp flavour 20 mg and 50 mg.

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.

On the basis of being generics of a reference medicinal product, no further information is required as it has already been presented for the reference product.

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 Medicinal 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.

Quality changes

Summary of change (DE/V/0142/001-003/DC)	**Section updated in Module 3**	**Approval date**
Change in the shelf-life of the finished product (DE/V/0142/001-003/IB/002)	N/A	06/06/2014
Change in the shelf-life of the finished product Change in the shelf life after first opening the bottle (DE/V/0142/IB/004/G)	N/A	24/03/2016