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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

Cefabactin 50 mg tablets for dogs and cats
Cefabactin 250 mg tablets for dogs and cats
Cefabactin 500 mg tablets for dogs
Cefabactin 1000 mg tablets for dogs

Created: August 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0201/001-004/DC
Name, strength and pharmaceutical form	Cefabactin 1000/500/250/50 mg tablets for dogs (and cats)
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater Nederland
Active substance(s)	Cefalexine monohydrate
ATC Vetcode	QJ01DB01
Target species	Dogs and cats
Indication for use	Treatment of infections in dogs and cats caused by bacteria susceptible to cefalexin such as: Respiratory tract infections, especially bronchopneumonia, caused by *Staphylococcus aureus, Streptococcus spp., Escherichia coli* and *Klebsiella spp.* Urinary tract infections caused by *Escherichia coli, Proteus spp.* and *Staphylococcus spp.* Skin infections in cats caused by *Staphylococcus spp.* and *Streptococcus spp.* and skin infections in dogs caused by *Staphylococcus spp.*

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).

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	5 May 2016
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, 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.

I. SCIENTIFIC OVERVIEW

Cefabactin is a generic application according to Article 13. The reference product is Cefabactin 50 mg smakelijke tabletten voor honden en katten, marketed by AST Beheer B.V. in the NL since 1994-01-19, marketing authorisation number REG NL 115298. The initial application for Cefabactin 50 mg smakelijke tabletten voor honden en katten was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The tablets contain 50 - 250 - 500 or 1000 mg Cefalexin (as monohydrate) and the following core excipients: Lactose monohydrate, Potato starch, Silica, Yeast, Chicken flavour and Magnesium stearate.

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

The tablets are packed in PVC/PE/PVDC-Alu blisters, each containing 10 tablets.

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

According to the current guideline the bioequivalence study can be waived because the Cefabactin tablets are identical (composition, quality of ingredients and manufacturing) to their reference products.

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. However, suitable pre-approval validation results on two production scale batches of the common blend, divided in the four tablet strengths, have been provided.

The tests performed during production are described.

C. Control of Starting Materials

The active substance Cefalexine monohydrate is an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The CEP procedure has been employed.

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.

Chicken flavour and Yeast comply to EC Flavouring Regulation 1334/2008. All other excipients are in conformity with the Ph.Eur. requirements.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

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 has been provided demonstrating compliance with the specification.

F. Stability

The retest period of 48 months for Cefalexine hydrate (compacted) when stored under the approved conditions is assessed by the EDQM as part of the CEP procedure.

Stability data on the finished product have been provided in accordance with applicable VICH guidelines. According to the stability results provided the claimed shelf life of 36 months can be granted for the Cefabactin tablets.
An in-use period of 4 days can be granted for de divided tablets.

G. Other Information

Cefabactin 1000/500/250/50 mg tablets for dogs (and cats)	NL/V/0201/001-004/DC
Le Vet Beheer B.V.	DCP
	Publicly available assessment report

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years Shelf-life after first opening the immediate packaging: 4 days.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

The pharmaco-toxicological aspects of this product is/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 / the environment / consumers.

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 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.

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 Vetrinary 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 (Application number	**Section updated in Module 3**	**Approval date**
Change the name of the veterinary medicinal product to: Cefabactin 50 mg tablets for dogs and cats (AT, BE, BG, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK) Cefatab flavour 50 mg tablets for dogs and cats (DE) Cefabactin vet 50 mg tablets for dogs and cats (DK, FI, IS, NO, SE, EE, LT, LV) Cefabactin 250 mg tablets for dogs and cats (AT, BE, BG, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK) Cefatab flavour 250 mg tablets for dogs and cats (DE) Cefabactin vet 250 mg tablets for dogs and cats (DK, FI, IS, NO, SE, EE, LT, LV) Cefabactin 500 mg tablets for dogs (AT, BE, BG, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK) Cefatab flavour 500 mg tablets for dogs (DE) Cefabactin vet 500 mg tablets for dogs (DK, FI, IS, NO, SE, EE, LT, LV) Cefabactin 1000 mg tablets for dogs (AT, BE, BG, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SI, SK, UK) Cefatab flavour1000 mg tablets for dogs (DE) Cefabactin vet 1000 mg tablets for dogs (DK, FI, IS, NO, SE, EE, LT, LV) (NL/V/0201/001-004/IB/001)	All sections updated	4 January 2017
Introduction of a new Pharmacovigilance system (DDPS)	N/A	12 July 2019