College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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NL/V/0186/001-003/DC

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Final

Amoxibactin (vet) 50/250/500 mg tablets for dogs (and cats)

Date: 2-11-2017

MODULE 1

PRODUCT SUMMARY

Dutch Application numbers	NL 114510, 114511, 114513
EU Procedure number	NL/V/0186/001-003/DC
NL Case numbers registration	369314, 369319, 369320
Names, strengths and pharmaceutical form	Amoxibactin (vet) 50 mg tablets for dogs and cats Amoxibactin (vet) 250 mg tablets for dogs Amoxibactin (vet) 500 mg tablets for dogs
Applicant	Le Vet Beheer BV, Wilgenweg 7, 3421 TV Oudewater, The Netherlands
Active substance(s)	Amoxicillin trihydrate
ATC Vetcode	QJ01CA04
Target species	Dogs (and cats)
Indication for use	Treatment of infections

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website:

https://www.diergeneesmiddeleninformatiebank.nl/nl/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended (Generic).
Date of completion of the original decentralised procedure	24-9-2014
Concerned Member States for original procedure	AT, BE, CY, CZ,DK, EE, EL, ES, FI, FR, HU, IE, IS, IT, LT, LU, LV, NO,PL, PT, RO, SE, SK, UK

I. SCIENTIFIC OVERVIEW

Amoxibactin (vet) 50_250_500 mg tablets for dogs (and cats) are 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 products can be safely used in the target species; the slight reactions observed are indicated in the SPC.
Amoxibactin (vet) 50_250_500 mg tablets for dogs (and cats) 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 products was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting the marketing authorisations.
The safety and efficacy aspects of Amoxibactin (vet) 50_250_500 mg tablets for dogs (and cats) are based on bioequivalence with the Reference products Amoxibactin 50_250_500 mg smakelijke tabletten (REG NL 2232_2233 and 10113 respectively)
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, warnings and contraindications are indicated in the SPC.

II. QUALITY ASPECTS

A. Composition

The tablets contain 57.5mg, 287.5 mg and 575.0 mg ammoxicilline trihydrate equivalent to 50 mg, 250 mg or 500 mg amoxicillin and the following core excipients: Lactose monohydrate, Colloidal silicon dioxide, Sodium starch glycolate (type A), Magnesium stearate, Microcrystalline cellulose, Yeast and Chicken flavour.
The tablet is cross scored and meant to be broken into equal halves or quarters.
The products are packed in PVC/PE-PVDC-Al 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.
A bioequivalence study is waived since it is similar to the reference product.

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 three pilot scale batches have been provided.

The tests performed during production are described

C. Control of Starting Materials

The active substance is amoxicillin trihydrate is an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.
A CEP 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 with the exception of the yeast and chicken flavour which have been adequately specified.

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

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

Lactose monohydrate is produced from milk which is sourced from healthy animals in the same condition as milk for human consumption and that the calf's rennet used complies with the public statement of the EMEA.

The magnesium stearate is of vegetable origin.

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 has been assessed by the EDQM in order to be granted a CEP.

Stability data on the finished product have been provided in accordance with applicable European guidelines. According to the stability results provided the claimed shelf life of 36 months(is update after variation) and in use shelf life of divided tablets of 4 days and storage conditions: Do not store above 30°C; Any unused tablet portion should be returned to the

open blister, can be granted. A photostability study has been performed demonstrating the drug product is not light sensitive.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

*III. SAFETY ASSESSMENT (*PHARMACO-TOXICOLOGICAL)

As these products are generic applications according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests or of the pre-clinical and clinical trials tests are not required.

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. Additional statements have been added, based on increased knowledge and the current state of science. Adverse events, warnings and contraindications are indicated in the SPC.

User Safety

As these products are generic applications according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests or of the pre-clinical and clinical trials tests are not required.

The applicant has provided a user safety assessment and proposed some additional (standard) warnings.

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.

III.B Residues documentation

Not applicable as the products are intended for cats and dogs.

IV. CLINICAL ASSESSMENT (EFFICACY)

As these products are generic applications according to Article 13, and bioequivalence with a reference product has been demonstrated (identical), results of safety tests or of the pre-clinical and clinical trials tests are not required.

V. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are 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 products for humans and the environment are 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.

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 (Application number)	**Section updated in Module 3**	**Approval date**
Shelflife (NL/V/0186/001-003/IB/001/G)	Updated	28-1-2016