FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fungiconazol 200 mg tablets for dogs
Canizol vet 200 mg tablets for dogs (DK, FI, IS, NO, SE, EE, LT, LV, PL)

Fungiconazol 400 mg tablets for dogs
Canizol vet 400 mg tablets for dogs (DK, FI, IS, NO, SE, EE, LT, LV, PL)

Date: 09/09/2014

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0263/001-002/DC
Name, strength and pharmaceutical form	Fungiconazol 200 mg / 400 mg tablets for dogs Canizol vet 200 mg / 400 mg tablets for dogs (DK, FI, IS, NO, SE, EE, LT, LV, PL)
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater The Netherlands
Active substance(s)	Ketoconazole
ATC Vetcode	QJ02AB02
Target species	Dogs
Indication for use	Treatment of dermatomycoses due to the following dermatophytes: - *Microsporum canis,* - *Microsporum gypseum,* - *Trichophyton mentagrophytes.*

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

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	23/07/2014
Concerned Member States for original procedure	AT, BE, CZ, DK, EE, EL, ES, FI, HU, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK, HR.

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 products Fungiconazol 200 mg and Fungiconazol 400 mg respectively contain 200,0 mg/tablet and 400 mg/tablet, ketoconazole as the active substance and excipients microcrystalline cellulose, sodium starch glycolate, sodium laurilsulfate, dried yeast, chicken flavour, colloidal anhydrous silica and magnesium stearate.

The container/closure system is a blister made of film of PVC/PE/PVDC and aluminium film. 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.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is ketoconazole, 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.
A shelf-life of the subdivided tablets as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

The formulations of the 200mg and 400mg tablets of the tested product are homothetic.
The applicant has provided an *in vivo* bioequivalence study comparing the 200 mg tested product and KETOFUNGOL 200 MG TABLETS FOR DOGS.
An *in vitro* comparative dissolution study between the 200 tablets, the 400 mg tablets and KETOFUNGOL 200 MG TABLETS FOR DOGS was also provided.
The tested products can be considered as bioequivalent with the reference product KETOFUNGOL 200 MG TABLETS FOR DOGS marketed by LILLY FRANCE.

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

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

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.

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.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

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.

Resistance

The applicant has documented the resistance part of the dossier with adequate scientific publications.

Warnings and precautions are listed on the product literature.

IV.B Clinical Studies

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 of the tested product are based on the reference product documentation.

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.