Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Mitex ear drops and cutaneous suspension for dogs and cats

Date: 21/10/2015

Last update: 11/11/2019

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DVR: 2112611

Modules 1-3 reflect the scientific discussion for the approval of Mitex Ohrentropfen und Suspension zur Anwendung auf der Haut für Hunde und Katzen. The procedure was finalised on 22.01.2015. For information on changes after this date please refer to module 4.

MODULE 1

PRODUCT SUMMARY

EU procedure number	AT/V/0014/001/DC
Name, strength and pharmaceutical form	Mitex, 5.0 mg/0.5293 mg/23.0 mg/ml, ear drops and cutaneous suspension
Applicant	Richter Pharma AG Feldgasse 19 4600 Wels Austria
Active substance(s)	Miconazole nitrate Prednisolone acetate Polymyxin B sulfate
ATCvet code	QS02CA01
Target species	Dogs and cats
Indication for use	For the treatment of otitis externa and small localised superficial skin infections in dogs and cats caused by infections with the following miconazole and polymyxin B sensitive bacteria and fungi: • Gram-positive bacteria – Staphylococcus spp. – Streptococcus spp. • Gram-negative bacteria – Pseudomonas spp. – Escherichia coli • Yeasts and fungi – Malassezia pachydermatis – Candida spp. – Microsporum spp. – Trichophyton spp. Treatment of Otodectes cynotis infestations where there is concurrent infection with miconazole and polymyxin B sensitive pathogens.

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
Reference medicinal product	Surolan 5,0 mg/0,5293 mg/23,0 mg/ml, Ohrentropfen, Suspension zur Anwendung auf der Haut für Hunde und Katzen
Date of completion of the original decentralised procedure	22.01.2015
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LV, NL, NO, PL, PT, RO, SE, SK, 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.

The applicant has provided a detailed description of the pharmacovigilance system which fulfils the requirements of Directive 2001/82/EC, as amended. Based on the information provided the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains:

Active substances:

Miconazole nitrate 23.0 mg (equivalent to 19.98 mg miconazole)

Prednisolone acetate 5.0 mg (equivalent to 4.48 mg prednisolone)

Polymyxin B sulfate 0.5293 mg (equivalent to 5500 IU polymyxin B sulfate)

Excipients:

Silica, colloidal anhydrous Paraffin

liquid

The container is a dropper container of white, opaque LDPE with white, opaque HDPE screw cap.

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 at a licensed manufacturing site.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substances are Miconazole nitrate, Prednisolone acetate and Polymyxin B sulfate, established substances described in the European Pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substance specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with these specifications have been provided.

Scientific data and/or certificates of suitability issued by the EDQM 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.

D. Control on intermediate products (pharmaceuticals)

Not applicable.

E. 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<s> have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substances 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 stability of 3 months if stored below 25° is supported.

G. Other Information

None

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

Since the application is made in accordance with Article 13(1) of Directive 2001/82/EC, as amended, for a generic veterinary medicinal product, data on pharmacodynamics and pharmacokinetics are not required. The data submitted are in accordance with the requirements of the applicable European bioequivalence guideline.

III.A Safety Testing

Pharmacological Studies

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

Toxicological Studies

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the overall risk after exposure to the product is low, it is not expected to pose a risk for the user if used as recommended in the SPC.

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

Environmental Risk Assessment

Phase I:

The environmental risk assessment can stop in Phase I because the product is used in companion animals only.

Conclusion:

Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

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.

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, pharmacodynamic and pharmacokinetic studies are not required.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, tolerance studies are not required.

Resistance

The bibliography / information provided suggests that the intended target bacterial species are susceptible. Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

Since the application is made in accordance with Article 13 (1) of Directive 2001/82/EC as amended by Directive 2004/28/EC, on the basis of being a generic of a reference medicinal product, data on clinical efficacy are not required.

Laboratory Trials

As this is a generic application according to Article 13, and bioequivalence with the reference product has been demonstrated, laboratory studies are not required as they have already been presented for the reference product.

Field Trials

The applicant has provided bibliographical data which show that the product is efficacious when used according to the SPC.

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 Veterinary 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.

Significant changes

Summary of change **(Application number)**	**Approval date**
Extension of the shelf life of the finished product as packaged for sale from 21 to 24 months. (AT/V/0014/001/IB/001)	10/07/2015
This marketing authorization was extended to another MS (SI) and therefore reassessed. (AT/V/0014/001/E/001)	05/12/2017
This marketing authorisation was renewed unlimited. (AT/V/0014/001/R/001)	20/09/2019