College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALIZED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dermanolon 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution for dogs and cats

Created: January 2020

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0205/001/DC
Name, strength and pharmaceutical form	Dermanolon 1.77 mg/ml + 17.7 mg/ml cutaneous spray, solution for dogs and cats
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater Nederland
Active substance(s)	Triamcinolone acetonide / Salicylic acid
ATC Vetcode	QD07XB02
Target species	Dogs and Cats
Indication for use	Symptomatic treatment of seborrheic dermatitis

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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).

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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 decentralized procedure	23 November 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

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.

Dermanolon is a generic application. The reference product for this application is Dermanolon oplossing voor cutaan gebruik voor honden en katten, registered in The Netherlands with marketing authorisation number REG NL 117324, of the company AST Beheer B.V. since 8 June 2015. The Reference Product Dermanolon, REG NL 117324 is an informed consent of the product Depocort Lotion, registered in The Netherlands since 21 November 1991 (Marketing Authorisation Holder is AST Beheer B.V., marketing authorisation number is REG NL 3541). Depocort Lotion, REG NL 3541 is the product for data protection. The initial application for Depocort Lotion was assessed before there was a requirement to have a public assessment report.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The cutaneous solution contains 1.77 mg/ml Triamcinolone Acetonide and 17 mg/ml Salicylic Acid as active substances and the following core excipients:

Benzalkonium Chloride, Ethanol 96% and Purified Water.

The solution packed in 50, 75 and 100 ml white HDPE bottles with a white PP spray pump and cap.

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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 product *Dermanolon cutaneous solution* is identical (composition, quality of ingredients and manufacturing) 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 at a licensed manufacturing site.

The product is manufactured using conventional manufacturing techniques. However, suitable pre-approval validation results on two production scale batches including all fill volumes have been provided

The tests performed during production are described.

C. Control of Starting Materials

The active substances Triamcinolone Acetonide and Salicylic Acid are established active substance described in the European Pharmacopoeia.

Triamcinolone Acetonide and Salicylic Acid are manufactured in accordance with the principles of good manufacturing practice.

The CEP procedure has been employed to both active substances.

The active substance specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has been provided.

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. 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 has been provided demonstrating compliance with the specification.

F. Stability

The retest periods are stated on the CEPs.

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The stability results of the product as packaged for sale do not support the claimed shelf-life of 36 months. The stability results currently provided allow only for a shelf-life of 30 months. The applicant should substantiate the claimed shelf-life of 3 years with additional supportive stability data.

G. Other Information

None.

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 supported by the risk assessments in the application, and are adequate to ensure safety of the product to users and the environment.

User Safety

The applicant has provided an user safety assessment in compliance with the relevant guideline which resulted in the following warnings in the product literature:

This product contains triamcinolone acetonide, salicylic acid and ethanol and may be harmful to children after accidental ingestion. Do not leave the product unattended. In case of accidental ingestion seek medical advice immediately and show the package leaflet or label to the physician.

This product may be harmful to the unborn child and can be absorbed through the skin. Pregnant women and women of childbearing potential should not handle this product or restrain the animal during treatment and should avoid contact with the treated animal until 4 hours after the application".

This product may be irritating to skin or induce hypersensitivity reactions. People with known hypersensitivity to corticosteroids or salicylic acid should avoid contact with the product.

Avoid skin contact with the product. Wear single-use impermeable gloves when handling the product including rubbing in the affected skin of the animal or restraining the animal during treatment. If contact occurs, wash hands or exposed skin and seek medical advice in case of hypersensitivity reactions or if irritation persists.

This product may be irritating to the eyes. Avoid contact with the eyes including hand-to-eye contact. If contact occurs, rinse with clean water. If eye irritation persists, seek medical advice and show the package leaflet or label to the physician.

This product may be harmful after inhalation, especially for people with asthma. Spray in well-ventilated area. Avoid breathing in the spray-mist.

Treated animals should not be handled and children should not be allowed to play with treated animals until the application site is dry. It is recommended that recently treated animals should not be allowed to sleep with owners, especially children.

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

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in individual non-food animals.

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.

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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.

Summary of change (Application number)	**Section updated**	**Approval date**
Introduction of a new Pharmacovigilance system (NL/V/xxxx/WS/021)	N/A	12 July 2019