College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats

NL/V/0204/001/DC

Created: October 2020

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0204/001/DC
Name, strength and pharmaceutical form	Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution
Applicant	Le Vet Beheer B.V Wilgenweg 7 3421 TV Oudewater
Active substance(s)	Triamcinolone acetonide salicylic acid
ATC Vetcode	QD07XB02
Target species	Dogs and cats
Indication for use	Otitis externa Symptomatic treatment of seborrhoeic dermatitis of the auricle.

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	23 November 2016
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Finland, France, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia , Slovenia, Spain, Sweden, United Kingdom

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 reference product for Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution is “Recicort oordruppels, oplossing voor honden en katten”, registered in The Netherlands under REG NL 117323, of the company AST Beheer B.V. This product was registered since 8 June 2015 and has been withdrawn since 3 September 2018. The reference product Recicort, REG NL 117323 was an informed consent of the product Depocort Lotion, registered in The Netherlands under REG NL 3541 since 21 November 1991. The Marketing Authorisation Holder is AST Beheer B.V. Depocort Lotion REG NL 3541 is the product for data protection. Depocort Lotion has been withdrawn in The Netherlands since 6 June 2019.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The cutaneous solution contains 2 mg Triamcinolone Acetonide and 20 mg Salicylic Acid as active substances and the following core excipients: Benzalkonium Chloride, Ethanol 96% and Purified Water.

20 and 50 ml; LDPE bottle, white; with LDPE dropper and cap.

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 Recicort ear drops 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 from 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.

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. 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

Stability data on the active substance<s> 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.

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 pharmacological and toxicologial 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 and the environment.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the following risks are acceptable:

- the risks for the user when administrating the product, when wearing gloves
- the risks for the user, including children, due to contact with the treated animal

The risk due to accidental ingestion by children and the risk due to administration of the product or contact with an treated animal by pregnant women or women of childbearing potential should be taken into account.

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 non-food animals.

Recicort	NL/V/0204/001/DC
Le Vet Beheer B.V.	DCP
	Publicly available assessment report

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	**Section updated**	**Approval date**
Changes to the Adverse Event sections of the SPC and Package Leaflet to implement the outcome of a Product Safety Update Report. (NL/V/0204/001/IA/001)	N/A	11 April 2019
Introduction of a new Pharmacovigilance system (NL/V/xxxx/WS/021)	N/A	12 June 2019