MEB agency / Veterinary Medicinal Products Unit

The Netherlands

College ter Beoordeling van Geneesmiddelen (CBG)
Medicines Evaluation Board (MEB)

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Prednicortone 5 mg and 20 mg tablets for cats and dogs

April 2018

heeft opmaak toegepast: Nederlands (standaard)

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0190/001-002/DC
Name, strength and pharmaceutical form	Prednicortone 5 mg and 20 mg tablets for dogs and cats.
Applicant	Le Vet Beheer B.V. Wilgenweg 7 3421 TV Oudewater The Netherlands
Active substance(s)	Prednisolone
ATC Vetcode	QH02AB06
Target species	Dogs and cats.
Indication for use	For the symptomatic treatment or as adjunct treatment of inflammatory and immune-mediated diseases in dogs and cats.

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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	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	20 May 2015.
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, NL, 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.

The safety and efficacy aspects of *Prednicortone 5 mg and 20 mg tablets for dogs and cats* are based on bioequivalence with the Dutch reference products *Prednoral 5 mg smakelijke tabletten voor honden en katten* (REG NL 2909) and *Prednoral 20 mg smakelijke tabletten voor honden en katten* (REG NL 10098). Warnings statements and precautions are adopted from the reference products. Additional statements have been added, based on increased knowledge and the current state of science.

II. QUALITY ASPECTS

A. QUALITATIVE AND QUANTITATIVE PARTICULARS

The tablets contain 5 mg or 20 mg prednisolone and the following core excipients:

Yeast (dried), chicken flavour, lactose monohydrate, powdered cellulose, sodium starch glycolate (type A) and magnesium stearate.

The tablet is cross scored and meant to be broken in halves or quarters.

The products are packed in PVC/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 biowaiver has been claimed. Comparative dissolution profiles at three different pH's i.e. 1.2, 4.5 and 7.5 between test and reference product substantiate the waiver.

B. DESCRIPTION OF THE MANUFACTURING METHOD

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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. Suitable pre-approval validation results on four production scale batches have been provided.
The tests performed during production are described.

C. CONTROL OF STARTING MATERIALS

The active substance prednisolone is an established active substance described in the European Pharmacopoeia.

Certificates of suitability issued by the EDQM have been provided.

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. The heat seal laquer from each supplier complies with EU Regulation 10/2011.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

D. CONTROL TESTS DURING THE MANUFACTURING PROCESS

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 finished product have been provided in accordance with applicable VICH guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions. According to the stability results provided the claimed shelf life of 36 months can be granted for both Prednicorton 5 mg and 20 mg tablets.

G. OTHER INFORMATION

None.

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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 toxicologcal, pharmacological and residue tests are not required.

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users, consumers and the environment.

III.A Safety Testing

User Safety

Being a generic procedure the applicant refers to the reference product for information on this section. Additionally, the applicant has provided a user safety assessment. Combined with increased knowledge and the current state of science, warning statements and precautions have been added to the product literature, ensuring safety to users of the product.

Environmental Risk Assessment

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.

Conclusion
Based on the data provided, the environmental risk assessment can stop in 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.

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 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 (Application number)	**Section updated in Module 3**	**Approval date**
NL/V/0190/001-002/IA/001/G Replacement of flavouring agent.	A, C.	2 Oktober 2015.
NL/V/0190/001-002/IB/002 Change in the invented name of the medicinal product (only in Germany).	-	6 June 2016
NL/V/0190/001-002/IB/003 Change in the invented name of the medicinal product (only in Poland).	-	28 Oktober 2016
NL/V/0190/002/R/001 Renewal	-	4 July 2020