ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Isaderm 5 mg/g + 1 mg/g Gel for Dogs [CZ, IE, PL, SK, UK]
Isaderm vet 5 mg/g + 1 mg/g Gel for Dogs [BE, NL]

PuAR correct as of 16/07/2018 when RMS was transferred to IE. Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0480/001/DC
Name, strength and pharmaceutical form	Isaderm 5 mg/g + 1 mg/g Gel for Dogs
Applicant	Dechra Veterinary Products A/S Mekuvej 9 DK-7171 Uldum Denmark
Active substance(s)	Fusidic acid Betamethasone (as valerate)
ATC Vetcode	QD07CC01
Target species	Dogs
Indication for use	For the topical treatment of surface pyoderma in the dog such as acute moist dermatitis (‘hot spots’) and intertrigo (skin fold dermatitis).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (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	29 January 2014
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Belgium, Czech Repuplic, Ireland, The Netherlands, Poland, Slovakia

I. SCIENTIFIC OVERVIEW

Isaderm is a cutaneous gel presented in 15 g or 30 g tubes. It contains 5 mg/g fusidic acid and 1 mg/g betamethasone. The product is for topical treatment of surface pyoderma in the dog, for conditions such as acute moist dermatitis ('hot spots') and intertrigo, (skin fold dermatitis). 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.[1] This was a generic application in accordance with Article 13 (1) of Directive 2001/82/EC as amended. The reference product was Fuciderm Gel 0.05% w/w Fusidic Acid, 0.1% Betamethasone, marketed in the UK since 1995. The Marketing Authorisation Holder for the reference product is the same for the proposed product.

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 benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of product Characteristics.

II. QUALITY ASPECTS

A. Composition

The product contains 5 mg/g fusidic acid and 1mg/g betamethasone. The excipients are methylparahydroxybenzoate (E218), propylparahydroxybenzoate, carbomer, polysorbate 80, dimeticone, sodium hydroxide (for pH adjustment) and purified water.

The container/closure system consists of an internally lacquered aluminium tube for 15 g or 39 g closed with a white HDPE screw cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of preservative are justified. 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 substances are fusidic acid and betammethsone, established active substances described in the European Pharmacopoeia (Ph. Eur). 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 material. Batch analytical data demonstrating compliance with this specification have been provided. Acceptable certificates of suitability were provided for both active substances.

All excipients are described in the Ph. Eur, and are well established for use in veterinary medicinal products. Suitable documentation was provided with regard to the acceptability of the packaging.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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.

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 substances and finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

- Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
- Shelf life after first opening of the immediate packaging: 6 weeks.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Do not store above 30°C. Do not refrigerate or freeze.

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, toxicological tests are not required. An acceptable user risk assessment was submitted.

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.

III.A Safety Testing

User Safety

The applicant provided a user risk assessment in compliance with the relevant guideline which showed that any associated risks were the same as those of the reference product. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

- Corticosteroids may produce irreversible effects in the skin; they can be absorbed and may have harmful effects, especially with frequent and extensive contact or in pregnancy. Pregnant women should take special care to avoid accidental exposure. Always wear single-use disposable gloves when applying this product to animals.
- Wash hands after having applied the product.
- Care should be taken to avoid accidental ingestion by a child. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.

Ecotoxicity

The applicant provided a Phase I environmental risk assessment in compliance with the relevant guideline. The product is for use in individual dog and is therefore not expected to pose undue risk to the environment. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (1), efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product. Exemption from providing bioequivalence studies was claimed under section 7.1(d) of the guideline for the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.2) which states that there is no requirement to provide further data to demonstrate bioequivalence to the reference product if:-

d) The formulations are identical (identical active substances and excipients as well as physiochemical properties [e.g. identical concentration, dissolution profile, crystalline form, pharmaceutical form and particle size and particle distribution with identical manufacturing process]).

The SPC is identical to that of the reference product. The Marketing Authorisation Holder of the proposed product is the same as that of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

As this was generic application and the proposed product is deemed to be identical to the reference product, no data were required for this section.

Resistance

Comment was provided by the applicant with regard to the current state of resistance to fusidic acid by the target pathogens. The SPC carries suitable warning.

IV.B Clinical Studies

As this was generic application and the proposed product is deemed to be identical to the reference product, no data were required for this section.

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 benefit/risk 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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)