Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Suxilon 1.5g granules for top dressing (only for UK)
Danilon equidos 1.5 g Oral Granules for horses and ponies (PL)
Danilon equidos 1.5 g Granules for horses and ponies (AT/DE)
Danilon equidos 1.5 g/10 g Granules for horses and ponies (NO)
Danilon equidos 1.5 g Granules (BE, CZ, EE, IS, HU, LV, LT RO, SK, SI)
Danilon Equidos (DK)

Date: 15 March 2018

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0192/001
Name, strength and pharmaceutical form	Danilon equidos 1.5 g Granules for horses and ponies
Applicant	Ecuphar Veterinaria S.L.U. Avenida Rio de Janeiro, 60-66, planta 13 E-08016 Barcelona Spain
Active substance(s)	Suxibuzone (microencapsulated)
ATC Vetcode	QM01AA90
Target species	Horses and ponies
Indication for use	Treatment of pain and inflammation associated with musculo-skeletal conditions in the horse *eg* osteoarthritic conditions, bursitis, laminitis and soft tissue inflammation.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

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	18 May 2011
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	Austria, Belgium, Czech Republic, Denmark, Estonia, Germany, Hungary, Iceland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia, Slovenia, United Kingdom (former RMS)

I. SCIENTIFIC OVERVIEW

Suxilon 1.5g granules for top dressing is authorised for use in horses and ponies for the treatment of pain and inflammation associated with musculo-skeltal conditions for example osteoarthritic conditions, bursitis, laminitis and soft tissue inflammation. The product is intended for oral administration only and contains suxibuzone (microencapsulated) 1.5 g per 10 g sachet. The product is supplied in cartons of 18 x 10 g or 60 x 10 g coated paper, aluminium foil and polyethylene sachets with 5 g spoon and 2.5 g increment dosing device. The recommended dosage rate for horses is 12.5 mg of suxibuzone/kg/day i.e. for a 480 kg bodyweight horse, the contents of 2 sachets should be administered twice daily for 2 days, followed by 1 sachet twice daily for three days. Ponies should receive only half the dosage rate recommended for horses.

This application for a MA[1] for a generic product was submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC and Directive 299/9/EC. Bioequivalence is claimed with the reference product, Danilon equidos 1.5 g granules for top dressing, which was authorised in the UK in August 2001. The applicant has claimed exemption from bioequivalence studies in accordance with exemption 4.c) of the Guidelines for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products.

[1] Marketing Authorisation

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[2]. The product is safe for the user and for the environment, when used as recommended. Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation. 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.

II. QUALITY ASPECTS

A. Composition

The product contains the active substance suxibuzone (microencapsulated) and excipients quinoline yellow (E104), mannitol, sucrose, povidone K30, sodium saccharin and ethyl cellulose 20.

The product is presented in cartons of 18 x 10 g or 60 x 10 g coated paper, aluminium foil and polyethylene sachets with 5 g spoon and 2.5 g increment dosing device.

The choice of formulation is justified.

The product is an established pharmaceutical form and its development has been 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

[2] Summary of Product Characteristics

The active substance, suxibuzone, is an established active substance and supporting data have been provided in the form of an active substance master file. A certificate of analysis from the manufacturer for three batches were provided, demonstrating compliance with the specification and the monograph of the European Pharmacopoeia.

All excipients, with the exception of quinoline yellow, are the subject of monographs in the European Pharmacopoeia. Compliance with the requirements of the pharmacopoeia is therefore applied as the specification for each of these ingredients. The yellow colour, quinoline yellow (E104), complies with European Directive 2008/128/EC for the purity criteria concerning colours for use in foodstuffs. This is considered acceptable.

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

All components of the product have been demonstrated to comply with relevant guidelines on minimising the risk of transmitting animal spongiform encephalopathy agents via veterinary medicines.

E. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

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.

G. Stability

Active substance:
Data have been provided which indicate that the active substance is stable when stored in the appropriate container under appropriate conditions. The retest period of four years is justified.

Finished product:
Data have been provided which indicate that the finished product is stable for 4 years.
The product should be used within 7 days after first opening of the sachet.
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H. Genetically Modified Organisms

Not applicable.

J. Other Information

Special precautions for storage:

- After opening a sachet re-seal as well as possible between doses.
- This medicinal product does not require any special storage conditions.

Shelf-life:

- Shelf life of the veterinary medicinal product as packaged for sale: 4 years
- Shelf life after first opening of the sachet: 7 days.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

The application was submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product, Danilon Equidos 1.5 g Granules for Top Dressing, has been demonstrated. Therefore, results of pharmacological, toxicological and clinical trials are not required.

User Safety

The applicant has submitted a user risk assessment addressing the different routes of exposure and in particular by inhalation. The product has a low dusting potential and is not a skin or eye irritant and did not show any sensitization potential.

The following precautions are listed on the SPC and product literature:

- Wear suitable gloves.
- Wash hands after use.
- Use in a well-ventilated area.
- Avoid inhaling any dust when opening sachet and mixing with feed.
- In case of accidental contact with eyes, wash immediately with plenty of clean water.
- In case of accidental ingestion, seek medical advice immediately and show this label to the physician.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guidelines. The product will be administered to equines for treatment of musculo-skeletal disorders. Animals will be treated in small numbers on an individual basis. Exposure of the environment will not be extensive and the assessment of environmental risk can end at Phase I. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

III.B Residues documentation

The application was submitted in accordance with Article 13(1) of Directive 2001/82/EC as amended by Directive 2004/28/EC and Directive 299/9/EC, on the basis that the product has been demonstrated to be a generic and therefore results of residues studies are not required.

Withdrawal Periods

Not to be used in animals intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

IV. CLINICAL ASSESSMENT (EFFICACY)

Suxilon 1.5g granules for top dressing has been demonstrated as quantitatively and qualitatively the same as the reference product, Danilon Equidos 1.5g Granules. Therefore the claim for exemption 4b) EMEA/CVMP/016/00] from providing bioequivalence studies, and, in accordance with Article 13(1), the exemption from providing further preclinical and clinical data, is acceptable.

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 Medicinal 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.

•	15 March 2018	Change of RMS from UK to DE
•	16 October 2017	Introduction of a new pharmacovigilance system.
•	11 May 2017	Addition of an alternative manufacturing site for the active substance
•	20 January 2017	Change in distributor details from Laboratorios Dr. ESTEVE, S.A. to Ecuphar Veterinaria S.L.U.
•	15 December 2016	Change in name and address of the manufacturer responsible for batch release.
•	01 December 2016	Change of MAH, from Laboratorios Dr. Esteve, S.A. to Ecuphar Veterinaria S.L.U.
•	02 June 2016	Renewal – UK as RMS