College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

TRICHOBEN, Lyophilisate and solvent for suspension for injection for cattle

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0233/001/DC
Name, strength and pharmaceutical form	TRICHOBEN, Lyophilisate and solvent for suspension for injection for cattle
Applicant	Kernfarm B.V. De Corridor 14D 3621 ZB Breukelen The Netherlands
Active substance(s)	Trichophyton verrucosum strain Bodin 1902
ATC Vetcode	QI02AP01
Target species	Cattle
Indication for use	For preventive and therapeutic treatment of trichophytosis in cattle from one day of age.

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MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website:

http://mri.medagencies.org/veterinary/

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	28th of February 2018
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	BE

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, the consumer of foodstuffs from treated animals 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.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains at least 3.125 x 10^6 Colony forming units of *Trichophyton verrucosum* strain Bodin 1902 and the excipients Sodium chloride, gelatine and sucrose. The solvent consists of phosphate buffered saline.

The container is a 10 ml hydrolytic class I glass vial closed with bromobutyl stoppers and aluminium covers or flip off caps. The diluent is supplied in 10, 50 or 100 ml hydrolytic class I or class II glass vials closed with chlorobutyl rubber stoppers and aluminium caps or flip of covers.

The choice of the vaccine strain is justified, the product does not contain an adjuvant or a preservative which is common and justified in live vaccines.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

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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 active substance is manufactured according to standard methods for the culture of fungi. Growth is harvested, homogenised and mixed with the lyophilisation medium. After filling the product is lyophilised according to standard methods. The diluent is manufactured by a simple process of mixing and subsequently sterilised.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is *Trichophyton verrucosum* strain Bodin 1902, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

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.

Scientific data 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.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Control tests during production

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

E. Control Tests on the Finished Product

The tests performed on the final product conform to the relevant requirements; any deviation from these requirements is justified. The tests include in particular: appearance, sterility, potency, pH, vacuum, residual moisture and reconstitution for the lyophilisate and appearance, extractable volume, sterility, pH and airtightness for the diluent.
The demonstration of the batch to batch consistency is based on the results of 3 batches produced according to the method described in the dossier.

F. Stability

The active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

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Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its 3 year shelf life when stored under the approved conditions.

G. Other Information

Not applicable

III. SAFETY ASSESSMENT

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of safety tests are not required, except an Environmental Risk Assessment

The quality and safety aspects of this product is/are identical to the reference product.

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

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

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, 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 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.

None