Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Trichovec, Lyophilisate and Solvent for Suspension for Injection for Cattle

Date Created: September 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Trichovec, Lyophilisate and Solvent for Suspension for Injection for Cattle
Applicant	Animal Health Distributors Limited Tullow Industrial Estate Bunclody Road Tullow Carlow R93WOD8 Ireland
Active substance(s)	Live *Trichophyton verrucosum*, strain Bodin 1902
ATC Vetcode	QI02AP01
Target species	Cattle
Indication for use	For the prophylactic immunisation of cattle from 1 day of age onwards to reduce skin lesions caused by *T. verrucosum* and to prevent shedding of *T. verrucosum* from the site of infection.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	13/06/2023

I. SCIENTIFIC OVERVIEW

This application is for a full marketing authorisation in accordance with Article 12(3).

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, any reactions observed are indicated in the SPC.[1] The product is safe for the user, the consumer of foodstuffs from treated animals and the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy [2] 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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains live *Trichophyton verrucosum*, strain Bodin 1902 and the excipients sodium chloride, gelatine, sucrose, potassium chloride, disodium phosphate dodecahydrate, potassium dihydrogen phosphate and water.

The container/closure system consists of Type 1 glass vials closed with bromobutyl rubber stoppers and aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and the absence of preservative are justified.

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

II.B. Method of Preparation of the Product

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of: preparation, homogenisation and lyophilisation.

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

II.C. Control of Starting Materials

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

Biological starting materials used are in compliance with the relevant Ph. Eur. or Certificate of Analysis. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur.

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

The packaging complies with Ph. Eur.

II.C.4. Substances of Biological Origin

Scientific data and/or 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.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.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 are: appearance, purity, determination of CFU number, pH, vacuum, residual humidity, reconstitution and identity tests.

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. Other supportive data provided confirm the consistency of the production process.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: use immediately.

Store and transport refrigerated (2°C-8°C).
Protect from frost.
Protect from light.

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose, an overdose, and the repeated administration of one dose in the target animal is demonstrated. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant Ph. Eur.

Effects on reproductive performance were examined: can be used during pregnancy.

There are no data suggesting that this product might adversely affect the immune system of the vaccinated animal or its progeny therefore a specific study was not carried out.

For each live strain included in the vaccine specific studies were carried out to describe the spread, dissemination, reversion to virulence, biological properties, recombination or genetic reassortment of the vaccine strain.

A withdrawal period is proposed based on data from a dissemination study performed in a non-target species. A withdrawal period for meat of 14 days is proposed for the vaccine.

No specific assessment of the interaction of this product with other medicinal product was made. Therefore, an appropriate warning in the SPC is included.

Field studies

The safety of the repeated administration of one dose, and the effect of administration on gestation period in the target animal is demonstrated.

Ecotoxicity

The applicant provided a Phase 1 environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

The assessment concluded that the product will not enter the environment directly. 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)

Clinical Studies

Laboratory Trials

The efficacy of the product has been demonstrated in laboratory studies in accordance with the relevant requirements.

Onset and Duration of Immunity

The applicant has provided two laboratory studies to support the onset of immunity of the vaccine and one to support the duration. It was concluded that the onset of immunity is 1 month, and the duration is at least 5 years.

Field Trials

Two studies were provided that investigated the efficacy after challenge and the therapeutic efficacy of vaccination in experimentally infected animals. It was confirmed that the claim for a reduction in clinical signs and infection is accepted.

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 of the product is favourable.

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.

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