United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bovilis Nasalgen-C Nasal Spray, Lyophilisate and Solvent for Suspension for Cattle

Date Created: November 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bovilis Nasalgen-C Nasal Spray, Lyophilisate and Solvent for Suspension for Cattle, Nasal spray, lyophilisate and solvent for suspension
Applicant	MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ
Active substance(s)	Bovine coronavirus (live)
ATC Vetcode	QI02AD10
Target species	Cattle
Indication for use	For the active immunisation of cattle from the day of birth onwards to reduce clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus.

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	30/8/2023

I. SCIENTIFIC OVERVIEW

This is a full application for a GB 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, any reactions observed are indicated in the SPC.[1] 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 [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 bovine coronavirus (strain CA25) and the excipients veggie medium, hydrolysed gelatine, pancreatic digest of casein, sorbitol, disodium phosphate dihydrate.

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

The choice of the vaccine strain is justified.

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

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

II.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. The manufacturing method consists of: propagation, harvest, mixing and blending and freeze-drying.

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 bovine coronavirus (BCV, strain CA25), a novel active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production comply with the relevant pharmacopoeias.

Biological starting materials used are in compliance with the relevant monographs and are appropriately screened for the absence of extraneous agents according to the Ph. Eur Guidelines.

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

Certificates of analysis have been provided for materials of non-biological origin.

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

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

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, solubility, vacuum test, BCV identity, potency, absence of mycoplasma spp., sterility and residual moisture.

The demonstration of the batch to batch consistency is based on the results of three 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.

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

The in-use shelf-life of the reconstituted vaccine is supported by the data provided.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale:
Lyophilisate: 2 years.
Solvent (2 ml): 3 years.
Solvent (10, 20, 40, 100 ml): 5 years.

Shelf life after reconstitution according to directions: 24 hours.

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Store below 25 °C if stored independently from the lyophilisate.
Do not freeze.

Reconstituted vaccine:
Store at room temperature.

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 in two GLP-compliant studies. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines. Some minor adverse effects were observed, but no particular safety concerns arose.

No investigation of effect on reproductive performance was conducted because the vaccine is not intended for this category of animals.

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.

Specific studies were carried out to describe the spread, dissemination, reversion to virulence or recombination of the vaccine strain.

The active substance and excipients used are allowed substances included in Table 1 of the Commission regulation No. 37/2010 and do not require an MRL. Based on this information, no withdrawal period is proposed.

The interaction of the vaccine with Bovilis INtranasal RSP Live was studied. Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovilis INtranasal RSP Live. The vaccines should be given into different nostrils. The product information of that veterinary medicinal product should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Field studies

A study was carried out to demonstrate safety. Sixty calves were administered a single intranasal dose of Bovilis Nasalgen-C into one nostril and one of Bovilis INtranasal RSP Live into the other. Minor adverse effects were observed. The study confirmed that the non-mixed administration of both products is well tolerated. The study also confirmed the safety of the single products.

Ecotoxicity

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

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.

A challenge was carried out with two different challenge viruses which produced mild upper respiratory tract signs. Study reports for seven studies in the target animal were provided. It was concluded that the veterinary medicinal product reduces clinical signs and efficacy was determined.

Onset of Immunity

Two onset of immunity (OOI) studies were presented which featured challenge at 5 days post vaccination. The OOI was determined to be 5 days.

Duration of Immunity

Studies were provided which showed that the vaccinated animals were statistically significantly different from the unvaccinated controls for clinical signs. The duration of immunity was concluded to be 12 weeks.

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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