



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

DrySeal 2.6 g Intramammary Suspension for Cattle

Date Created: November 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	DrySeal 2.6 g Intramammary Suspension for Cattle
Applicant	Elanco Europe Ltd Form 2, Bartley Way Bartley Wood Business Park Hook United Kingdom
Active substance	Bismuth subnitrate
ATC Vetcode	QG52X
Target species	Cattle
Indication for use	Prevention of new intramammary infections throughout the dry period. In cows considered likely to be free of sub-clinical mastitis, the veterinary medicinal product can be used on its own in dry cow management and mastitis control.

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	Generic hybrid application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10a) as amended.
Date of conclusion of the procedure	9/08/24

I. SCIENTIFIC OVERVIEW

This is a generic application where the reference product is Orbeseal Dry Cow 2.6 g Intramammary Suspension which has been authorised since 2002. It is considered a hybrid application as it is not possible to determine bioequivalence using plasma levels.

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 efficacy² 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 bismuth subnitrate and the excipients liquid paraffin, aluminium di tri stearate and colloidal anhydrous silica.

The container/closure system consists of LDPE syringes with LDPE dual caps and LDPE plungers. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation 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 regulatory guidelines.

¹ SPC – Summary of product Characteristics.

² Efficacy – The production of a desired or intended result.

II.B. Description of the Manufacturing Method

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 regulatory guidelines.

II.C. Control of Starting Materials

The active substance is bismuth subnitrate, an established active substance described in the European Pharmacopoeia. 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.

The excipients are listed in Ph. Eur.
All packaging components comply with Ph. Eur.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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

Not applicable.

II.E. 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. Control tests on the finished product are those suitable for this pharmaceutical form.

II.F. Stability

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

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: use immediately.
This veterinary medicinal product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Bibliographical data has been provided which show that bismuth subnitrate acts by as a physical barrier against the entry of bacteria thereby reducing the incidence of new intramammary infections during the dry period. The applicant has provided bibliographical data which show that bismuth subnitrate is not absorbed from the mammary gland but resides as a seal in the teat until physically removed. Bioequivalence was accepted with the reference product.

Toxicological Studies

Not required due to the legal basis of the application.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:.

- This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes.
- Should skin or eye contact occur, wash the affected area thoroughly with water.
- If irritation persists, seek medical advice, and show the package leaflet or label to the physician.
- Bismuth salts have been associated with hypersensitivity reactions. If you know that you are allergic to bismuth salts, avoid using this veterinary medicinal product. If you develop symptoms following exposure, seek medical advice and show the package leaflet or the label to the physician.
- Wash hands after use.

- Disinfectant wipes:
The disinfectant wipes may cause skin and eye irritation due to the presence of isopropyl alcohol. Avoid eye contact. Avoid prolonged contact with skin. Avoid inhalation of the vapour. The wearing of gloves may prevent skin irritation.
- Wash hands after use.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The initial predicted environmental concentration (PEC) in soil is less than 100 µg/kg. Therefore a Phase II ERA was not required.

III.B.2 Residues documentation

Withdrawal Periods

Based on the data provided, a withdrawal period of 0 days for meat in cattle and 0 hours for milk are justified.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Not required due to the legal basis of the application.

IV.II. Clinical Documentation

Not required due to the legal basis of the application.

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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