Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Boviseal 2.6 g Intramammary Suspension for Cattle

Date Created: November 2016

PuAR correct as of 18/12/2018 when RMS was transferred to FR.
Please contact the RMS for future updates.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0410/001/DC
Name, strength and pharmaceutical form	Boviseal 2.6 g Intramammary Suspension for Cattle
Applicant	Continental Farmaceutica, Rue Laid Burniat, 1 1348 Louvain-la-Neuve Belgium
Active substance(s)	2.6g, bismuth subnitrate, heavy
ATC Vetcode	QG52X
Target species	Cattle (Dairy cows)
Indication for use	Prevention of new intramammary infections throughout the dry period. In cows considered likely to be free of sub-clinical mastitis, the product can be used on its own in dry cow management and mastitis control. Selection of cows for treatment with the product should be based on veterinary clinical judgement. Selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of sub-clinical mastitis or bacteriological sampling.

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	Informed Consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	25th July 2012
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Austria, Belgium, Denmark, France, Germany, Italy, Luxembourg, The Netherlands, Portugal, Spain.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Orbeseal Dry Cow Intramammary Suspension. The initial application for Orbeseal Dry Cow Intramammary Suspension was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. 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.

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