IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Boviseal Dry Cow Intramammary Infusion

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Boviseal Dry Cow Intramammary Infusion
Active substance	Bismuth Subnitrate 2.6g per 4g syringe
Marketing Authorisation Holder	Zoetis Belgium S.A. 2nd Floor, Building 10 Cherrywood Business Park, Loughlinstown Co Dublin Ireland
Date of Authorisation	29thJune 2008
Target species	Dairy cows at the end of lactation
Indication for use	Boviseal is indicated for the prevention of new intramammary infections throughout the dry period. This results in a reduction in the incidence of subclinical mastitis in cows at calving, and of clinical mastitis in the dry period and the subsequent lactation (for at least 60 days after calving). It is recommended that Boviseal be used as part of a herd approach to dry cow management and mastitis control. Cows considered likely to be free of subclinical mastitis should be given Boviseal at drying off according to the criteria below. Other animals should be managed in accordance with an approved mastitis control plan or specific veterinary advice. For practical purposes, selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of

	subclinical mastitis or bacteriological sampling. It is particularly important that, prior to treatment, an individual cell count be obtained from any cow with a history of clinical mastitis during the previous lactation. As a guide, cows with an average cell count less than 200,000 cells/ml before drying off may be given Boviseal. A minor increase (cell count up to 250,000 cells/ml) during the last 4 weeks before drying off is normal and may be ignored. In case of doubt, veterinary advice should be sought.
ATCvet code	QJ51X Antibacterials for intramammary use.

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The initial application for the product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to Section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. 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 HPRA website.

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.

Quality Changes

Summary of change **(Application number)**	**Approval date**
Addition of 200 syringe presentation (CRN7021147)	21st July 2015