IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

TruSeal 2.6 g Intramammary suspension for cattle

PRODUCT SUMMARY

Name, strength and pharmaceutical form	TruSeal 2.6 g Intramammary suspension for cattle
Active substance	Bismuth subnitrate, heavy
Marketing Authorisation Holder	Univet Limited, (10990), (LOC-100020114), Tullyvin, Cootehill, Co. Cavan., Ireland
Legal basis of application	Informed consent application (Article 21 of Regulation 2019/6)
Date of Authorisation	06/09/2024
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 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.
ATC vet code	QG52X

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 Regulation (EU) 2019/6. 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 quality, safety and efficacy aspects of this product are identical to Ubroseal Blue Dry Cow 2.6 g Intramammary suspension for cattle (VPA 10990/049/001). Cross reference is therefore made to the public assessment report for Ubroseal Blue Dry Cow 2.6 g Intramammary suspension for cattle which is available on the HPRA website.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the 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

Not applicable.