IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Bovimast DC, 500 mg cloxacillin/syringe, Intramammary suspension

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bovimast DC, 500mg cloxacillin/syringe, Intramammary suspension
Active substance(s)	Cloxacillin (as Cloxacillin Benzathine)
Marketing Authorisation Holder	Bimeda Animal Health Limited, 2, 3, & 4 Airton Close, Tallaght, Dublin 24, Ireland.
Legal basis of application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Date of Authorisation	8th July 2004
Target species	Cattle
Indication for use	For routine use in cows at drying off, to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period. Bovimast DC contains cloxacillin which is active against the following major pathogens associated with mastitis: Penicillin resistant and sensitive *Staphylococcus* spp., *Micrococcus* spp., *Streptococcus agalactiae* and *Corynebacterium* spp.
ATCvet code	QJ51CF

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (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 relevant articles of 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 the 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.

Safety/Efficacy Changes

Summary of change (Application number)	**Approval date**
Changes to withdrawal periods (milk, meat and offal) (CRN00FDK5)	23/08/2024