IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Alamycin LA 200 mg/ml Solution for Injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Alamycin LA 200 mg/ml Solution for Injection
Active substances(s)	Oxytetracycline
Applicant	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate Monaghan Ireland
Legal basis of application	Full application (Article 12(3) of Directive No 2001/82/EC)
Date of Authorisation	01/10/1988
Target species	Cattle, Pigs, Sheep
Indication for use	Oxytetracycline is active against a wide range of Gram-positive and Gram-negative pathogenic bacteria, certain rickettsia and the larger viruses. Alamycin LA is indicated in the treatment of a wide range of common systemic, respiratory and local infections caused by or associated with organisms sensitive to oxytetracycline in cattle, sheep and pigs.
ATCvet code	QJ01AA06

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation processand 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 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**
Change to composition (excipients) of the veterinary medicinal product (CRN008DJY).	23/12/2020
Change in the specification parameters of the finished product (CRN008DJY).	23/12/2020
Change in the immediate packaging of the finished product (CRN008DJY).	23/12/2020

Safety/Efficacy Changes

Summary of change (Application number)	**Approval date**
CRN008DJY - Changes to the withdrawal period	23/12/2020