IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Promox LA 150 mg/ml Suspension for Injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Promox LA 150 mg/ml suspension for injection
Active substance	Amoxicillin (as trihydrate)
Marketing Authorisation Holder	Interchem (Ireland) Ltd., 29 Cookstown Industrial Estate, Dublin 24.
Legal basis of application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of Authorisation	8th June 2012
Target species	Cattle, sheep and pigs
Indication for use	For the treatment of diseases caused by a wide range of Gram-positive and Gram-negative organisms in cattle, sheep and pigs.
ATCvet code	QJ01CA04

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 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 quality / safety / efficacy aspects of this product are identical to Trioxyl LA 150 mg/ml suspension for injection (VPA 10990/010/001). The initial application for Trioxyl LA 150 mg/ml suspension for injection was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV CLINICAL ASSESSMENT (EFFICACY)

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.

Changes
None.