IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Resflam 300/20 mg/ml Solution for Injection for Cattle

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Resflam Solution for Injection for Cattle
Active substances	Oxytetracycline dihydrate Flunixin meglumine
Marketing Authorisation Holder	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate Monaghan Ireland
Legal basis of application	Informed consent application in accordance with Article 13(c)of Directive 2001/82/EC as amended.
Date of Authorisation	25/09/2009
Target species	Cattle
Indications	For the treatment of acute respiratory disease caused by oxytetracycline sensitive *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida* where an anti-inflammatory and anti-pyretic effect is required.
ATCvet code	QJ01AA56

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 website.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Hexasol LA Solution for Injection (VPA 10999/073/001).The initial application for Hexasol LA 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 Resflam solution for injection demonstrated adequate evidence of quality, safety and efficacy for the approved indication 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.