IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Framomycin 150 mg/ml Solution for Injection

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Framomycin 15% Solution for Injection
Active substance(s)	Framycetin
Marketing authorisation holder	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany
Marketing authorisation number	VPA 10397/009/001
Date of authorisation	1st October 1988
Indication and target species	As an adjunct to treatment of acute mastitis with systemic involvement in dairy cows, caused by organisms sensitive to framycetin. Should be given in conjunction with an appropriate intramammary preparation
Method of sale and supply	Prescription Only Medicine
Additional supply restrictions	None

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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.

I. SCIENTIFIC OVERVIEW

The initial application for Framomycin 15% Solution for Injection 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 V for significant post-approval changes which are important for the quality, safety and efficacy of the product.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that Framomycin 15% Solution for Injection demonstrated adequate evidence of efficacy for the approved indication(s) as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet are updated on a continuous basis to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA's website.
This section contains information on significant changes made after approval which are important for the quality, safety or efficacy of the product.