IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Clindacyl 300 mg Tablets for Dogs

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Clindacyl 300 mg Tablets for Dogs
Active substance	Clindamycin hydrochloride
Marketing Authorisation Holder	Chanelle Pharmaceuticals Manufacturing Limited Loughrea Co. Galway Ireland
Legal basis of application	Well established veterinary use application in accordance with Article 13a of Directive 2001/82/EC as amended.
Date of Authorisation	30th July 2008
Target species	Dogs
Indication for use	For the treatment of wounds, abscesses and oral cavity/dental and osteomyelitis
ATCvet code	QJ01FF01 Clindamycin

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

This section reflects the initial scientific discussion on the approval of Clindacyl 300 mg Tablets for Dogs.
This application is a duplicate of the authorisation for Clinacin 300 mg Tablets for Dogs. The initial application for the original product, Clinacin Tablets for Dogs, was assessed and authorised 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.

None.