IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Marbocyl P 20 mg Tablets

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Marbocyl P 20 mg Tablets
Active substance(s)	Marbofloxacin
Marketing Authorisation Holder	Vetoquinol Ireland Limited, First Floor, Segrave House, 19/20 Earlsfort Terrace, Dublin 2, Ireland
Legal basis of application	Full dossier application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of Authorisation	19/04/04
Target species	Dogs
Indication for use	**Dogs** Marbofloxacin tablet is indicated in the treatment of: Skin and soft tissue infections (intertrigo, folliculitis, impetigo, furunculosis, cellulitis) caused by susceptible strains. Lower and upper urinary tract infections (UTI) associated or not with prostatitis or epididymitis caused by susceptible strains. Respiratory tract infections caused by susceptible strains.
ATCvet code	QJ01MA93 Marbofloxacin

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 initial application for Marbocyl P 20 mg Tablets 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 Marbocyl P 20 mg Tablets demonstrated adequate evidence of efficacy for the approved indication(s) 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.

Safety/Efficacy Changes

Summary of change **HPRA case reference number 7007133**	**Approval date**
Removal of product interaction warning Bibliographical data was provided in support of the removal of the theophylline warning. Based on the data and argumentation submitted, the removal of the warning was justified.	24/02/2010