IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Amoxinsol 50 % w/w powder for oral solution

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Amoxinsol 50 % w/w powder for oral solution
Active substance	Amoxicillin trihydrate
Marketing Authorisation Holder	Vetoquinol S.A., Magny-Vernois 70200 Lure France
Date of Authorisation	11/07/1995
Target species	Chickens, turkeys, ducks, pigs
Indication for use	Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin. Not effective against beta-lactamase producing organisms. Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies. Pigs: For the treatment of salmonellosis and pasteurellosis.
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 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 Amoxinsol 50 % w/w powder for oral solution 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 Amoxinsol 50 % w/w powder for oral solution 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.

Safety/Efficacy Changes

Summary of change **HPRA case reference number 7004859**	**Approval date**
Change in withdrawal period The Applicant submitted an application to change the meat withdrawal period to 1 day in chickens. A new residue depletion study was conducted in chickens. Based on the residue data submitted, a decrease in the meat withdrawal period for chickens from 2 days to 1 day was justified.	July 2009

Summary of change **HPRA case reference number 7006712**	**Approval date**
To add an additional method of administering the product to pigs The Applicant submitted an application to add an additional method of administering the product to pigs. A study demonstrating the solubility and stability of the product in liquid feed was presented. Additional user safety warnings were added to the product based on the information provided. This change in administration was not considered to affect the antimicrobial resistance profile, safety or efficacy of the product. Based on the data submitted, the method of administering the product to pigs by addition to a liquid feed instead of drinking water was justified.	July 2010