IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

WORMALL 2.265%w/v Oral Suspension

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Wormall 2.265% w/v Oral Suspension
Active substance(s)	Oxfendazole
Marketing Authorisation Holder	Coyle Veterinary Products
Date of Authorisation	30/5/1994
Target species	Cattle, sheep.
Indication for use	WORMALL is a broad spectrum anthelmintic for the treatment and control of mature and developing immature gastro-intestinal roundworms and lungworms and also tapeworms in cattle and sheep. WORMALL is ovicidal for strongyle eggs. For the treatment of cattle and sheep infested with benzimidazole susceptible strains of the following species: Gastro-Intestinal Roundworms: *Ostertagia* *Haemonchus* *Trichostrongylus* *Nematodirus (*including *N. battus)* *Cooperia* *Capillaris* *Oesophagostomum* *Chabertia* *Trichuris* Lungworms: *Dictyocaulus* Tapeworms: *Monezia* In cattle, it is also effective against inhibited larvae of *Cooperia spp.* and usually effective against inhibited/arrested larvae of *Ostertagia spp*.. In sheep, it is effective against inhibited/arrested larvae of *Nematodirus spp*., and benzimidazole susceptible *Haemonchus spp.* and *Ostertagia spp*..
ATCvet code	QP52AC02

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 the product 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 (EFFICACY)

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.

Safety/Efficacy Changes

Summary of change (Application number)	**Approval date**
Change to the sheep meat withdrawal period (CRN 7022141)	11/11/2015