IPAR

Publicly Available Assessment Report for a Veterinary Medicinal Product

Bob Martin Easy to Use Wormer Granules for Small Dogs

PRODUCT SUMMARY

Marketing authorisation number	10987/116/001
Name, strength and pharmaceutical form	Bob Martin Easy to Use Wormer Granules for Small Dogs
Active substance(s)	Fenbendazole
Marketing Authorisation Holder	Chanelle Pharmaceuticals Manufacturing Ltd Loughrea Co. Galway Ireland
Legal basis of application	13c informed consent
Date of Authorisation of procedure	27th June 1997
Target species	Dogs
Indication for use	For the treatment of immature and mature stages of nematodes of the gastro-intestinal and respiratory tracts of domestic dogs. It also has an ovicidal effect and is indicated for the following: For the treatment of gastrointestinal nematodes and cestodes of domestic dogs affected with Ascarid spp., Ancylostoma spp., Uncinaria spp., Trichuris spp., and Taenia spp. Also for the treatment of lungworm nematodes of domestic dogs affected with Oslerus (Filariodes) osleri.
ATCvet code	QP52AC13

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.

Changes

Summary of change	**Approval date**
Change to the MAH name from The Bob Martin Company to Bob Martin (UK) Ltd.	March 2007
Transfer of the MA to Chanelle Pharmaceuticals Manufacturing Ltd	July 2015