IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

ORAMEC Drench for Sheep 0.8 mg/ml

PRODUCT SUMMARY

Name, strength and pharmaceutical form	ORAMEC Drench for Sheep 0.8 mg/ml
Active substance	Ivermectin
Marketing Authorisation Holder	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55216 Ingelheim am Rhein Germany
Legal basis of application	Original authorisation based on full dossier.
Date of Authorisation	1st October 1989
Target species	Sheep
Indication for use	For the treatment and control of mixed infections of gastrointestinal roundworms, lungworms and nasal bot
ATCvet code	QP54AA01 Ivermectin

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 Oramec Drench for Sheep 0.8 mg/ml 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 Oramec Drench for Sheep 0.8 mg/ml 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	**Approval date**
Change in meat withdrawal period. In June 2005, the European Commission adopted a significantly increased ADI (600 µg /person) and modified MRLs for Ivermectin. For sheep, the MRLs for liver and fat increased (to 100 µg/kg) and a MRL of 30 µg/kg was set for kidney. Given the changes to the MRLs, a. 6 day withdrawal period can be accepted (based on the original residue data). HPRA case reference number 7001427	31st May 2007