IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Paramectin 1% Solution for Injection

PRODUCT SUMMARY

EU Procedure number	IE/V/0119/001/MR
Name, strength and pharmaceutical form	Paramectin 1% Solution for injection
Active substance	Ivermectin
Applicant	Norbrook Laboratories (Ireland) Limited Rossmore Industrial Estate Monaghan Ireland
Legal basis of application	Generic application in accordance with Article 5.10 a(iii) of Directive 81/851/EC.
Date of Authorisation	29th June 2001
Date of Completion of procedure	18th October 2001
Target species	Cattle (beef and non-lactating dairy cattle) and pigs
Indication for use	Endectocide
ATCvet code	QP54AA01
Concerned Member States	ES, IT & PT

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 the 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's website.

I. SCIENTIFIC OVERVIEW

The initial application for Paramectin 1% Injection was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. QUALITY ASPECTS

See section I.

III. SAFETY ASSESSMENT

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit /risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 7019269**	**Approval date**
Withdrawal period for meat and offal from pigs reduced from35 days to 18 days	28th May 2008