

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

Ecomectin 5 mg/ml Pour-on Solution for Cattle

PRODUCT SUMMARY

EU Procedure number	IE/V/0108/001/E/004
Name, strength and pharmaceutical form	Ecomectin 5 mg/ml Pour-on Solution for Cattle
Active substances(s)	Ivermectin
Applicant	ECO Animal Health Europe Limited 6th Floor South Bank House Barrow Street Dublin 4 D04 TR29 Ireland
Legal basis of application	Well-established use application (Article 13a of Directive No 2001/82/EC)
Date of <Authorisation / completion of procedure>	
Target species	Cattle
Indication for use	
ATCvet code	QP54AA01
Concerned Member States	

PUBLIC ASSESSMENT REPORT**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:***Safety/Efficacy Changes***

Summary of change (Application number)	Approval date
Introduction of changes to the SPC arising from the outcome of the Article 83 Referral for all veterinary medicinal products containing N-methyl pyrrolidone as an excipient, EMEA/V/A/146, (2023)2311 of 28 Mar 2023.	14/09/2023