

**IPAR**



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

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Qualimec Cattle Pour-on

**PRODUCT SUMMARY**

<b>EU Procedure number</b>	IE/V/0108/001/E/004
<b>Name, strength and pharmaceutical form</b>	Qualimec Cattle Pour-on
<b>Active substances(s)</b>	Ivermectin
<b>Applicant</b>	ECO Animal Health Europe Limited 6th Floor South Bank House Barrow Street Dublin 4 D04 TR29 Ireland
<b>Legal basis of application</b>	Not Currently Available
<b>Date of &lt;Authorisation / completion of procedure&gt;</b>	
<b>Target species</b>	Cattle
<b>Indication for use</b>	
<b>ATCvet code</b>	QP54AA01
<b>Concerned Member States</b>	

**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***

<b>Summary of change (Application number)</b>	<b>Approval date</b>
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