ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Molemec Pour-On for Cattle 5 mg/ml Pour-On Solution

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Molemec Pour-On for Cattle 5 mg.ml Pour-On Solution
Applicant	Merial Animal Health Ltd
Active substance(s)	Ivermectin
ATC Vetcode	QP54AA01
Target species	Cattle
Indication for use	For the treatment and control of gastro-intestinal nematodes, lungworms, eyeworms, warbles, chorioptic and sarcoptic mange and sucking and biting lice in beef and non-lactating dairy cattle. The product at the recommended dosage level of 500 ÿg ivermectin per kg bodyweight effectively controls the following parasites of cattle: **Gastrointestinal roundworms (adult and fourth stage larvae)**: *Ostertagia ostertagi* (including inhibited stage) *Haemonchus placei* *Trichostrongylus axei* *T. colubriformis* *Cooperia* spp. *Oesophagostomum radiatum* *Strongyloides papillosus* (adult) *Trichuris* spp. (adult) **Lungworms (adult and fourth stage larvae)**: Dictyocaulus viviparus **Eyeworms (adult):** *Thelazia* spp **Warbles** (parasitic stages): *Hypoderma bovis* *H. lineatum*

	Mange mites: *Sarcoptes scabiei* var. *bovis* *Chorioptes bovis* **Lice:** *Linognathus vituli* *Haematopinus eurysternus* *Solenopotes capillatus* *Damalinia bovis* The product given at the recommended dosage of 500 ÿg/kg bodyweight, controls infections with *Trichostrongylus axei* and *Cooperia* spp acquired up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days after treatment, and *Dictyocaulus viviparus* (lungworm) acquired up to 28 days after treatment. It also controls horn fly (*Haematobia irritans*) for up to 35 days after treatment. The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Ivomec Classic Pour-on for Cattle. The initial application for Ivomec Classic Pour-on for Cattle was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. 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.

MODULE 4

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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