ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Molemec Injection for Cattle and Sheep 10 mg/ml Solution for Injection

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Molemec Injection for Cattle and Sheep 10 mg/ml Solution for Injection
Applicant	Merial Animal Health Ltd
Active substance(s)	Ivermectin
ATC Vetcode	QP54AA01
Target species	Cattle and sheep
Indication for use	Indicated for the effective treatment and control of the following parasites of cattle and sheep: ***CATTLE*** **PARASITE** / **Adult** / **L4** / **Inhibited L4** **Gastrointestinal Roundworms** *Ostertagia lyrata* • • *Ostertagia ostertagi* • • • *Cooperia oncophora* • • *Cooperia pectinata* • • *Cooperia punctata* • • *Haemonchus placei* • • *Trichostrongylus axei* • • *Trichostrongylus colubriformis* • • *Bunostomum phlebotomum* • • *Oesophagostomum radiatum* • • *Strongyloides papillosus* • *Nematodirus helvetianus* • *Nematodirus spathiger* • *Trichuris* spp. • **Lungworms** *Dictyocaulus viviparus* • • **Eye Worms** *Thelazia* spp •

Warbles
Hypoderma bovis
H. lineatum

Mange Mites
Psoroptes ovis
Sarcoptes scabei var. *bovis*

Sucking Lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

The product may also be used as an aid in the control of biting lice *(Damalinia bovis)* and the mange mite *Chorioptes bovis,* but complete elimination may not occur.

Persistent Activity
Given at the recommended dosage of 1ml per 50kg bodyweight, the product
controls re-infection with the following nematodes up to the duration shown:

Parasite	**No. of Days After Treatment**
Barbers pole worm - *Haemonchus placei*	14
Small intestinal worm - *Cooperia* spp.	14
Hairworm – *Trichostrongylus axei*	14
Brown stomach worm - *Ostertagia ostertagi*	21
Nodular worm - *Oesophagostomum radiatum*	21
Lungworm – *Dictyocaulus viviparus*	28

To obtain optimal benefit from the persistent activity for grazing animals, it is recommended that calves which are set-stocked in the first grazing season
should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastroenteritis and lungworm disease throughout the grazing season, provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture.
Treated animals should continue to be monitored according to good husbandry practices.

SHEEP

PARASITE	Adult	L4	Inhibited L4
Gastrointestinal Roundworms			
Ostertagia circumcincta	•	•	•
O. trifurcata	•	•	
Haemonchus contortus	•	•	•
Trichostrongylus axei	•		
T. colubriformis	•	•	
T. vitrinus	•		
Cooperia curticei	•	•	
Oesophagostomum columbianum	•	•	
O. venulosum	•		
Nematodirus filicollis	•	•	
Chabertia ovina	•	•	
Trichuris ovis	•		
Lungworms			
Dictyocaulus filaria	•	•	
Protostrongylus rufescens	•		
Nasal Bots			
Oestrus ovis			
Mange Mites			
*Psoroptes ovis**			

Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

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 Injection for Cattle and Sheep (Ivermectin). The initial application for Ivomec Classic Injection for Cattle and Sheep (Ivermectin) 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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