Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Molemec Drench for Sheep 0.8 mg/ml Oral Solution

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Molemec Drench for Sheep 0.8 mg/ml Oral Solution
Applicant	Merial Animal Health Ltd
Active substance(s)	Ivermectin
ATC Vetcode	QP54AA01
Target species	Sheep
Indication for use	MOLEMEC Drench is indicated for the treatment and control of gastro-intestinal nematodes, lungworms and nasal bots of sheep. MOLEMEC Drench at the recommended dose rate of 200 mcg ivermectin per kg bodyweight provides effective control against the following parasites of sheep: **SHEEP** **Gastro-intestinal roundworms (adult and immature)**: *Haemonchus contortus* *Teladorsagia circumcincta* *Trichostrongylus* spp. *Cooperia* spp. *Nematodirus* spp. including *N. battus* *Strongyloides papillosus* *Oesophagostomum* spp. *Chabertia ovina* (Adults) Inhibited larval stages, benzimidazole resistant strains of *H. contortus* and *T. circumcincta* are also controlled. **Lungworms (adult and immature)**: *Dictyocaulus filaria* **Nasal bot (all larval stages):** *Oestrus ovis*

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 are identical to Oramec Drench (Ivermectin). The initial application for Oramec Drench (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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