



**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 Paste for Horses 18.7 mg/g Oral Paste

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Molemec Paste for Horses 18.7 mg/g Oral Paste
Applicant	Merial Animal Health Ltd
Active substance(s)	Ivermectin
ATC Vetcode	QP54AA01
Target species	Horses and donkeys
Indication for use	<p>The product is indicated for the treatment of parasitic infestations in horses and donkeys due to:</p> <p>Large strongyles <i>Strongylus vulgaris</i> (adults and arterial larval stages) <i>S. edentatus</i> (adults & tissue larval stages) <i>S. equinus</i> (adults) <i>Triodontophorus</i> spp. (adults) <i>Triodontophorus brevicauda</i> <i>Triodontophorus serratus</i> <i>Craterostomum acuticaudatum</i> (adults)</p> <p>Small Strongyles Adult and immature (fourth stage larvae) small strongyles or cyathostomes, including benzimidazole-resistant strains: <i>Coronocyclus</i> spp <i>Coronocyclus coronatus</i> <i>Coronocyclus labiatus</i> <i>Coronocyclus labratus</i> <i>Cyathostomum</i> spp. <i>Cyathostomum catinatum</i> <i>Cyathostomum pateratum</i> <i>Cylicocyclus</i> spp. <i>Cylicocyclus ashworthi</i> <i>Cylicocyclus elongatus</i> <i>Cylicocyclus insigne</i> <i>Cylicocyclus leptostomum</i> <i>Cylicocyclus nassatus</i> <i>Cylicocyclus radiatus</i> <i>Cylicostephanus</i> spp. <i>Cylicostephanus asymmetricus</i></p>

	<p><i>Cylicostephanus bidentatus</i> <i>Cylicostephanus calicatus</i> <i>Cylicostephanus goldi</i> <i>Cylicostephanus longibursatus</i> <i>Cylicostephanus minutus</i> <i>Cylicodontophorus</i> spp. <i>Cylicodontophorus bicornatus</i> <i>Gyalocephalus capitatus</i> <i>Parapoteriostomum</i> spp <i>Parapoteriostomum euproctus</i> <i>Parapoteriostomum mettami</i> <i>Petrovinema</i> spp <i>Petrovinema poculatum</i> <i>Poteriostomum</i> spp <i>Poteriostomum imparidentatum</i></p> <p>Pinworms (adult and immatures) <i>Oxyuris equi</i></p> <p>Ascarids (adults and third & fourth stage larvae) <i>Parascaris equorum</i></p> <p>Hairworms (adults) <i>Trichostrongylus axei</i></p> <p>Large-mouth stomach worms (adults) <i>Habronema muscae</i></p> <p>Neck threadworms (microfilariae) <i>Onchocerca</i> spp.</p> <p>Intestinal threadworms (adults) <i>Strongyloides westeri</i></p> <p>Stomach bots Oral and gastric stages of <i>Gastrophilus</i> spp.</p>
--	---

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 Eqvalan Oral Paste for Horses (Ivermectin 1.87% w/w). The initial application for Eqvalan Oral Paste for Horses (Ivermectin 1.87% w/w) 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.

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