ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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MUTUAL RECOGNITIONDECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Molemec Plus Paste for Horses 15.5 mg/g/ 77.5 mg/g Oral Paste
EQVALAN DUO EQUIPACK (FR)

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0455/001/MR
Name, strength and pharmaceutical form	Molemec Plus Paste for Horses 15.5 mg/g/ 77.5 mg/g Oral Paste
Applicant	Merial Animal Health Limited PO Box 327 Sandringham House Harlow Business Park Harlow Essex CM19 5TG United Kingdom
Active substance(s)	Ivermectin, Praziquantel
ATC Vetcode	QP54AA51
Target species	Horses
Indication for use	For the treatment of mixed cestode and nematode or arthropod infestations in horses. The following parasites of horses are sensitive to the antiparasitic effects of Molemec Plus Paste: **Adult Tapeworms***:* *Anoplocephala perfoliata* *Anoplocephala magna* **Large strongyles:** *Strongylus vulgaris* (adults and arterial larval stages) *Strongylus edentatus* (adults and tissue larval stages) *Strongylus equinus* (adults) *Triodontophorus* spp (adults) *Triodontophorus brevicauda* *Triodontophorus serratus* *Craterostomum acuticaudatum* (adults) ***Adult and immature (intraluminal fourth-stage larvae) of small strongyles or cyathostomes, including benzimidazole-resistant strains:*** *Coronocyclus* spp

	Coronocyclus coronatus *Coronocyclus labiatus* *Coronocyclus labratus* *Cyathostomum* spp *Cyathostomum catinatum* *Cyathostomum pateratum* *Cylicocyclus* spp *Cylicocyclus ashworthi* *Cylicocyclus elongatus* *Cylicocyclus insigne* *Cylicocyclus leptostomum* *Cylicocyclus nassatus* *Cylicodontophorus* spp *Cylicodontophorus bicornatus* *Cylicostephanus* spp *Cylicostephanus calicatus* *Cylicostephanus goldi* *Cylicostephanus longibursatus* *Cylicostephanus minutus* *Parapoteriostomum* spp *Parapoteriostomum mettami* *Petrovinema* spp *Petrovinema poculatum* *Poteriostomum* spp **Adult hairworms**: *Trichostrongylus axei* **Adult and immature (fourth stage Larvae) pinworms**: *Oxyuris equi* **Adult, third- and fourth-stage larvae of roundworms** (ascarids): *Parascaris equorum* **Microfilariae of neck threadworms**: *Onchocerca* spp **Adult intestinal threadworms**: *Strongyloides westeri* **Adult large-mouth stomach worms**: *Habronema muscae* **Oral and, gastric stages of bots**: *Gasterophilus* spp **Adult and immature (inhibited fourth stage larvae) lungworms**: *Dictyocaulus arnfieldi*

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition	27 June 2012.
Date product first authorised in the Reference Member State (MRP only)	05 July 2011
Concerned Member States for original procedure	France.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to the original product, Eqvalan Duo, Oral Paste. The initial application for the parent product 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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