ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Pramoxiquest Oral Gel for Horses and Ponies

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Pramoxiquest Oral Gel for Horses and Ponies
Applicant	Pfizer Ltd
Active substance(s)	Moxidectin
ATC Vetcode	QP54AB52
Target species	Horses
Indication for use	Indicated for the treatment of mixed cestodes and nematodes or arthropods infections, caused by moxidectin and praziquantel sensitive strains of: Large strongyles: Strongylus vulgaris (adult stages) Strongylus edentatus (adult stages) Triodontophorus brevicauda (adults) Triodontophorus serratus (adults) Triodontophorus tenuicollis (adults) Small strongyles (adults and intraluminal larval stages): Cyathostomum spp. Cylicocyclus spp. Cylicostephanus spp. Cylicodontophorus spp. Gyalocephalus spp. Ascarids: Parascaris equorum (adult) Other species: Oxyuris equi (adult stages) Habronema muscae (adults) Gasterophilus intestinalis (L2, L3) Gasterophilus nasalis (L2, L3) Strongyloides westeri (adults) Trichostrongylus axei (adults) Tapeworm (adults): Anoplocephala perfoliata

	Anoplocephala magna Paranoplocephala mammillana The egg reappearance period of small strongyles is 90 days. The veterinary medicinal product is effective against (developing) intramucosal L4 stages of small strongyles. At 8 weeks after treatment, early (hypobiotic) EL3 stages of small strongyles are eliminated.

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 13(c) of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Equest Pramox 19.5 mg/g + 121.7 mg/g Oral Gel.

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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