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

Moxiquest 18.92 mg/g Oral Gel for Horses & Ponies

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Moxiquest 18.92 mg/g Oral Gel for Horses & Ponies
Applicant	Pfizer Ltd
Active substance(s)	Moxidectin
ATC Vetcode	QP54AB02
Target species	Horses
Indication for use	The veterinary medicinal product is indicated for treatment of infections caused by moxidectin sensitive strains of: Large strongyles: *Strongylus vulgaris* (adults and arterial stages) *Strongylus edentatus* (adults and visceral 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 and larval stages) Other species: *Oxyuris equi* (adult and larval stages) *Habronema muscae* (adults) *Gasterophilus intestinalis* (L2, L3) *Gasterophilus nasalis* (L2, L3)

	Strongyloides westeri (adults) *Trichostrongylus axei* The veterinary medicinal product has a persistent efficacy of two weeks against small strongyles. The excretion of small strongyles eggs is suppressed for 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 are identical to Equest Oral Gel 18.92 mg/g Oral Gel for Horses and Ponies.

V 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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