IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Equipramox 19.5 mg/g + 121.7 mg/g oral gel

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0380/001
Name, strength and pharmaceutical form	Equipramox 19.5 mg/g + 121.7 mg/g oral gel
Active substance(s)	Moxidectin Praziquantel
Marketing Authorisation Holder	Zoetis Belgium S.A., 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co Dublin, Ireland
Legal basis of application	Informed consent application in accordance with Article 13 (c) of Directive 2001/82/EC as amended.
Target species	Horses
Indication for use	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* (adults) Other species: - *Oxyuris equi* (adult stages) - *Habronema muscae* (adults) - *Gasterophilus intestinalis* (L2, L3) - *Gasterophilus nasalis* (L2, L3) - *Strongyloides westeri* (adults) - *Trichostrongylus axei* (adult stages) Tapeworm (adults): - *Anoplocephala perfoliata* - *Anoplocephala magna* - *Paranoplocephala mammillana* The egg reappearance period of small strongyles is 90 days. The 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.
ATCvet code	QP54 AB52
Concerned Member States	United Kingdom

PUBLIC ASSESSMENT REPORT

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The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It

is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by HPRA leading to the approval of the product for marketing in Ireland.
The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to EQUEST PRAMOX ORAL GEL. The initial application for EQUEST PRAMOX ORAL GEL was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. QUALITY ASPECTS

See section I.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I.

IV. CLINICAL ASSESSMENT

See section I.

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. 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 HPRA website.