IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Promec 18.7 mg/g Oral Paste for Horses

"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/0474/001/DC
Name, strength and pharmaceutical form	Promec 18.7 mg/g Oral Paste for Horses
Active substances(s)	Ivermectin
Applicant	ECO Animal Health Europe Limited 6th Floor South Bank House Barrow Street Dublin 4 D04 TR29 Ireland
Legal basis of application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC, as amended.
Date of completion of procedure	17th April 2019
Target species	Horses
Indication for use	Treatment of nematode or arthropod infection due to: Large strongyles: *Strongylus vulgaris* (adults and L_4 stage larvae [arterial]) *Strongylus edentatus* (adults and L_4 stage larvae [tissue]) *Strongylus equinus* (adults) Small strongyles (including benzimidazole resistant strains): *Cyathostomum* spp.(adults and luminal L_4 stage larvae) *Cylicocyclus* spp. (adults and luminal L_4 stage larvae) *Cylicodontophorus* spp. (adults and luminal L_4 stage larvae) *Cylicostephanus* spp. (adults and luminal L_4 stage larvae) *Gyalocephalus* spp. (adults and luminal L_4 stage larvae) Ascarids: *Parascaris equorum* (luminal L_5 larvae and adults) Pinworms: *Oxyuris equi* (L_4 stage larvae and adults) Neck threadworms: *Onchocerca* spp. (microfilariae) Stomach bots: *Gasterophilus* spp. (oral and gastric stages)
ATCvet code	QP54AA01
Concerned Member States	ES, IT, PT & UK

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PUBLIC ASSESSMENT REPORT

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 the 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 Animec 18.7 mg/g oral paste for horses. The initial application for Animec 18.7 mg/g oral paste for horses 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.

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