

**IPAR**



**Publicly Available Assessment Report for a  
Veterinary Medicinal Product**

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Promec 18.7 mg/g Oral Paste for Horses

**PRODUCT SUMMARY**

<b>EU Procedure number</b>	IE/V/0474/001/DC
<b>Name, strength and pharmaceutical form</b>	Promec 18.7 mg/g Oral Paste for Horses
<b>Active substance(s)</b>	Ivermectin
<b>Applicant</b>	Acme Drugs S.r.l., Via Portella Della Ginestra 9 Cavriago RE, 42025 Italy
<b>Legal basis of application</b>	Informed consent application in accordance with Article 13c of Directive 2001/82/EC, as amended.
<b>Date of completion of procedure</b>	17th April 2019
<b>Target species</b>	Horses
<b>Indication for use</b>	<p>Treatment of nematode or arthropod infection due to:</p> <p>Large strongyles:  <i>Strongylus vulgaris</i> (adults and L<sub>4</sub> stage larvae [arterial])  <i>Strongylus edentatus</i> (adults and L<sub>4</sub> stage larvae [tissue])  <i>Strongylus equinus</i> (adults)</p> <p>Small strongyles (including benzimidazole resistant strains):  <i>Cyathostomum</i> spp.(adults and luminal L<sub>4</sub> stage larvae)  <i>Cylicocyclus</i> spp. (adults and luminal L<sub>4</sub> stage larvae)  <i>Cylicodontophorus</i> spp. (adults and luminal L<sub>4</sub> stage larvae)  <i>Cylicostephanus</i> spp. (adults and luminal L<sub>4</sub> stage larvae)  <i>Gyalocephalus</i> spp. (adults and luminal L<sub>4</sub> stage larvae)</p> <p>Ascarids:  <i>Parascaris equorum</i> (luminal L<sub>5</sub> larvae and adults)</p> <p>Pinworms:  <i>Oxyuris equi</i> (L<sub>4</sub> stage larvae and adults)</p> <p>Neck threadworms:  <i>Onchocerca</i> spp. (microfilariae)</p> <p>Stomach bots:  <i>Gasterophilus</i> spp. (oral and gastric stages)</p>
<b>ATCvet code</b>	QP54AA01
<b>Concerned Member States</b>	ES, IT, PT & UK

**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.