



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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Surrey KT15 3LS**

NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

Alonate-P 400 mg/ml Oral Paste for Horses and Ponies

Date Created: 8th June 2015

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Alonate-P 400 mg Oral Paste for Horses and Ponies
Applicant	Bimeda Animal Health Limited 2 / 3 / 4 Airton Close Tallaght Dublin 24 Ireland
Active substance	Pyrantel embonate
ATC Vetcode	QP52AF02
Target species	Horses and ponies
Indication for use	<p>Pyrantel embonate is a broad spectrum anthelmintic. Pyrantel embonate is indicated for use in the horse for the control and treatment of adult infections of large and small strongyles, Pinworms, Roundworms, Tapeworms.</p> <p>Pyrantel embonate has a broad spectrum of activity, including activity against:</p> <p>Large strongyles: <i>Strongylus vulgaris</i>, <i>S. edentatus</i>, <i>S. equinus</i>. Small strongyles: <i>Trichonema spp.</i> (<i>Cyathostomes</i>), <i>Triodontophorus spp.</i> Pinworms: <i>Oxyuris equi</i>, <i>Probstmayria vivipara</i>. Large roundworms: <i>Parascaris equorum</i>. Tape worms: <i>Anoplocephala perfoliata</i>.</p>

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
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I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Pyratape P Horse Wormer, 40% w/w Oral Paste. The initial application for Pyratape P Horse Wormer, 40% w/w Oral Paste was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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 of the product(s) is favourable.

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.

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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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