

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
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



# **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                     | 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.  Pyrantel embonate has a broad spectrum of activity, including activity against:  Large strongyles: Stronglylus vulgaris, S. edentatus, S. equinus. Small strongyles: Trichonema spp. (Cyathostomes), Triodontophorus spp. Pinworms: Oxyuris equi, Probstmayria vivipara. Large roundworms: Parascaris equorum. Tape worms: Anoplocephala perfoliata. |  |  |  |  |

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# **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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#### **PUBLIC ASSESSMENT REPORT**

| Legal basis of original | Informed consent application in accordance with |  |    |           |            |    |  |
|-------------------------|---|--|----|-----------|------------|----|--|
|                         | Article<br>amende                               |  | of | Directive | 2001/82/EC | as |  |

## 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.

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#### 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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