PYRANTEL EMBONATE

Alonate-P®

400 mg/g

Oral Paste for Horses and Ponies

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Pyrantel embonate

MARKETING AUTHORISATION HOLDER AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE
Cross Vetpharm Group Ltd.
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NAME OF THE VETERINARY MEDICINAL PRODUCT
Alonate-P® 400 mg/g Oral Paste for Horses and Ponies. Pyrantel embonate.

STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS
The product is a ready-to-administer, 400 mg/g oral paste formulation of pyrantel embonate active ingredient and 0.2 mg/g butylated hydroxytoluene as an antioxidant.

INDICATION(S)
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.

CONTRAINDICATIONS
Not for use in foals less than 4 weeks of age. Contraindicated in known sensitivity to pyrantel and in severely debilitated animals.

ADVERSE REACTIONS
Pyrantel embonate is safe for horses and ponies of all ages, including sucklings, pregnant mares and studs. Impaction of the small intestine may occur in foals, infected with high numbers of *Parascaris equorum*. Symptoms (colic) may be seen as soon as 30 minutes after treatment.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

TARGET SPECIES
Horses and Ponies

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Control and treatment of Strongyles, Oxyuris and Parascaris:

Alonate-P® should be used at a dose rate of 19 mg pyrantel embonate per kg bodyweight. The dosing programmes are as follows:

a) **FOALS (1-8 MONTHS OF AGE):**
dose every 4 weeks.

b) **HORSES (OVER 8 MONTHS OF AGE):**
dose every 6-8 weeks, but during the summer and autumn when at grass dose every 4-6 weeks. Always dose 3-4 days before turning out after in wintering.

c) **SUCKLER MARES:**
It has been shown that reduction of strongyle challenge to the suckling foal at pasture can be achieved by using clean pasture (re-seeded or not grazed the previous year by horses), dosing the mare 3-4 days before turning out and then at intervals of 2-4 weeks until the end of Autumn. Ideally mares with foals should go out to 'clean' pasture or, if this is not possible, delay turning them out until June.

The prescribed amount of Alonate-P® is deposited on the tongue of the animal and the animal allowed to swallow. The complete content of one syringe contains 11.4g pyrantel embonate (6 graduated doses of 1.9g) in 28.5g paste and is sufficient for the treatment of 600kg bodyweight. Each graduation of the syringe is sufficient for the treatment of 100kg body-weight.

CONTROL AND TREATMENT OF ANOPLOCEPHALA (TAPEWORM):
Alonate-P® should be used at a dose rate of 38mg pyrantel embonate per kg bodyweight (i.e. twice the dose used for stronglyes). The need for re-treatment may vary, but if considered necessary, should be carried out after an interval of 6 weeks.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

ADVICE ON CORRECT ADMINISTRATION
None

WITHDRAWAL PERIOD
Not to be used in horses and ponies intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Do not store above 25°C.
Protect from direct sunlight.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of that month.

SPECIAL WARNING(S)
Special warnings for each target species.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used. Resistance to pyrantel has been reported in cyathostomes in horses (also widespread in the USA and Canada). Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS
The same syringe should only be used to dose two animals if they are both healthy and are either running together, or are on the same premises and in direct contact with each other.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS
Direct contact with the skin should be avoided. Wash hands and any other parts of the body which comes into contact with the product after use. Avoid handling the product if you know you are hypersensitive to pyrantel

USE DURING PREGNANCY, LACTATION OR LAY
Alonate-P® is safe to give to pregnant and lactating mares provided the recommendations are followed.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS
Combined administration of pyrantel and levamisole or piperazine is not recommended.

OVERDOSE
Pyrantel embonate is of low acute oral toxicity. Oral doses of up to 2000mg/kg bodyweight in mice and rats and 1000mg/kg in dogs have produced no evidence of toxicity.

Pyrantel embonate, at dosages of up to 60mg/kg bodyweight, as base, (some 20 times the standard therapeutic dose) had no adverse effects on horses, ponies or foals. Monitoring included haematological parameters, and serum cholinesterase and glutamic oxaloacetic transaminase levels.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
16/03/2015

OTHER INFORMATION

POM-VPS

Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person
To be supplied only on veterinary prescription
For Animal Treatment Only.

Vm 12597/4062

AKKER®