

**PYRANTEL- pyrantel pamoate paste**  
**Durvet, Inc**

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**Read Entire Carton Carefully Before Using This Product**

**DESCRIPTION:**

Pyrantel Paste (pyrantel pamoate) is a pale yellow to buff paste containing 43.9% w/w pyrantel pamoate in an inert vehicle. Each syringe contains 3.6 grams pyrantel base in 23.6 grams paste. Each mL contains 171 mg pyrantel base as pyrantel pamoate.

**COMPOSITION:**

Pyrantel pamoate is a compound belonging to a family classified chemically as tetrahydropyrimidines. It is a yellow, water-insoluble crystalline salt of the tetrahydropyrimidine base and pamoic acid containing 34.7% base activity.

The chemical structure and name are given below:

Chemical Name:

(E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)-vinyl]-pyrimidine 4,4' methylenebis [3-hydroxy-2 naphtholate] (1:1)

**INDICATIONS FOR USE:**

For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*) in horses and ponies.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

**DOSAGE AND TREATMENT:**

Pyrantel Paste (pyrantel pamoate) is to be administered as a single oral dose of 3 mg pyrantel base per lb of body weight. The syringe has 4 weight mark increments. Each weight mark indicates the recommended dose for 300 lb of body weight.

<b>DOSAGE</b>		
<b>Body Weight Range</b>	<b>Volume</b>	<b>mg Pyrantel Base</b>
up to 300 lb	1/4 syringe	900 mg
301 - 600 lb	1/2 syringe	1800 mg
601 - 900 lb	3/4 syringe	2700 mg
901 - 1200 lb	1 full syringe	3600 mg

**Note:** Position ring-gauge over appropriate mark on plunger. Each mL contains 171 mg of pyrantel base as pyrantel pamoate.

**Do not underdose.** Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

For maximum control of parasitism, it is recommended that foals (2-8 months of age) be dosed every 4 weeks. To minimize the potential source of infection that the mare may pose to the foal, the mare should be treated 1 month prior to anticipated foaling date followed by re-treatment 10 days to 2 weeks after birth of foal. Horses and ponies over 8 months of age should be routinely dosed every 6 weeks.

### **ADMINISTRATION:**

After removing the cap, the paste should be deposited on the dorsum of the tongue. Introduce the nozzle end of the syringe at the corner of the mouth. Direct the syringe backwards and depress the plunger to deposit the paste onto the tongue. Given in this manner, it is unlikely that rejection of the paste will occur. Raising the horse's head sometimes assists in the swallowing process. When only part of the paste has been used, replace the cap on the syringe nozzle.

### **EFFICACY:**

Critical (worm count) studies in horses demonstrated that pyrantel pamoate paste administered at the recommended dosage was efficacious against mature infections of *Strongylus vulgaris* (>90%), *Oxyuris equi* (81%), *Parascaris equorum* (>90%), and small strongyles (>90%).

### **WARNINGS**

For oral animal use only. Do not use in horses intended for human consumption.

### **HUMAN WARNINGS:**

**Keep out of the reach of children.**

It is recommended that severely debilitated animals not be treated with this preparation.

**OTHER WARNINGS:** Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance. Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method). A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at



<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:30798-836	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)		PYRANTEL	3.6 g in 23.6 g	
<b>Product Characteristics</b>				
<b>Color</b>	yellow	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:30798-836-83	23.6 g in 1 SYRINGE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANADA	ANADA200350	03/01/2007		

**Labeler** - Durvet,Inc (056387798)

**Registrant** - Bimeda, Inc. (060492923)

### Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC Animal Health		256232216	manufacture

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Durvet,Inc