### **PYRANTEL PAMOATE-** pinwormtreatment suspension Neogen Corporation dba Columbia Laboratories

-----

### Active Ingredients (in each 1 tsp)

Pyrantel base: 250 mg (as Pyrantel Pamoate)

### **Purpose**

Pinworm treatment

### **Indication**

For the treatment of pinworms.

### Warnings

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center immediately.

**If you are pregnant or have liver disease,** do not take this product unless directed by a physician.

When using this product, abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these conditions persist, consult a physician.

### **Directions**

- Shake well before use.
- Adults, children 12 years of age and over, and children 2 years to under 12 years of age - oral dosage is a single dose of 5 milligrams of Pyrantel Base per pound (or 11 milligrams per kilogram) of body weight, not to exceed 1 gram (4 teaspoonfuls).

### WEIGHT

Less than 25 Pounds or under 2 years old 25 to 37 Pounds 38 to 62 Pounds

## DOSAGE(TAKEN AS A SINGLE DOSE)

Do not us unless directed by a physician ½ teaspoonful (125 mg) 1 teaspoonful (250 mg)

63 to 87 Pounds	1½ teaspoonfuls (375 mg)
88 to 112 Pounds	2 teaspoonfuls (500 mg)
113 to 137 Pounds	2½ teaspoonfuls (625 mg)
138 to 162 Pounds	3 teaspoonfuls (750 mg)
163 to 187 Pounds	3½ teaspoonfuls (875 mg)
188 Pounds and over	4 teaspoonfuls (1000 mg)

- Dosage information: Each 5 mL (1 teaspoonful) of Pyrantel Pamoate Suspension contains the equivalent of 250 mg of Pyrantel Base.
- Read package insert carefully before taking this medication.
- Take only according to directions and do not exceed the recommended dosage unless directed by a physician.
- Medication should only be taken one time as a single dose, do not repeat treatment unless directed by a physician.
- When one individual in a household has pinworms, the entire household should be treated unless otherwise advised.
- If any worms other than pinworms are present before or after treatment, consult a physician.
- If any symptoms or pinworms are still present after treatment, consult a physician.
- This product can be taken any time of day, with or without meals. It may be taken alone or with milk or fruit juice.
- Use of a laxative is not necessary prior to, during, or after medication.

### Other information

• Recommended storage: Store at temperature between 15°C - 30°C (59°F - 86°F).

### **Inactive Ingredients**

Citric Acid, Potassium Sorbate, Purified Water, USP, Sodium Benzoate, Sucrose, Vanilla Flavor, and Xanthan Gum

### Questions?

Call 859-254-1221 or toll-free 800-621-8829.

DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

### PYRANTEL PAMOATE ORAL SUSPENSION USP (Pyrantel base: 50 mg / mL)

### PINWORM TREATMENT

### **Drug Facts**

Active ingredient

### (in each 1 tsp)

Pyrantel base: 250 mg (as Pyrantel Pamoate)

### **Purpose**

Pinworm treatment

**Indication** For the treatment of pinworms.

### Warnings

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center immediately.

If you are pregnant or have liver disease, do not take this product unless directed by a physician.

When using this product, abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these conditions persist, consult a physician.

### **Directions**

- Shake well before use.
- Adults, children 12 years of age and over, and children 2 years to under 12 years of age - oral dosage is a single dose of 5 milligrams of Pyrantel Base per pound (or 11 milligrams per kilogram) of body weight, not to exceed 1 gram (4 teaspoonfuls).

WEIGHT	DOSAGE (TAKEN AS A SINGLE DOSE)
Less than 25 Pounds or under 2 years old	Do not us unless directed by a physician
25 to 37 Pounds	½ teaspoonful (125 mg)
38 to 62 Pounds	1 teaspoonful (250 mg)
63 to 87 Pounds	1½ teaspoonfuls (375 mg)
88 to 112 Pounds	2 teaspoonfuls (500 mg)
113 to 137 Pounds	2½ teaspoonfuls (625 mg)
138 to 162 Pounds	3 teaspoonfuls (750 mg)
163 to 187 Pounds	3½ teaspoonfuls (875 mg)
188 Pounds and over	4 teaspoonfuls (1000 mg)

- Dosage information: Each 5 mL (1 teaspoonful) of Pyrantel Pamoate Suspension contains the equivalent of 250 mg of Pyrantel Base.
- Read package insert carefully before taking this medication.
- Take only according to directions and do not exceed the recommended dosage unless directed by a physician.
- Medication should only be taken one time as a single dose, do not repeat treatment unless directed by a physician.
- When one individual in a household has pinworms, the entire household should be treated unless otherwise advised.
- If any worms other than pinworms are present before or after treatment, consult a

physician.

- If any symptoms or pinworms are still present after treatment, consult a physician.
- This product can be taken any time of day, with or without meals. It may be taken alone or with milk or fruit juice.
- Use of a laxative is not necessary prior to, during, or after medication.

### Other information

Recommended storage: Store at temperature between 15°C - 30°C (59°F - 86°F).

### **Inactive Ingredients**

Citric Acid, Potassium Sorbate, Purified Water, USP, Sodium Benzoate, Sucrose, Vanilla Flavor, and Xanthan Gum

Questions? Call 859-254-1221 or toll-free 800-621-8829.

### PYRANTEL PAMOATE

### READ THIS INSERT THOROUGHLY BEFORE TAKING THIS PRODUCT.

This brochure will tell you about pinworms and how to treat infections effectively with Pyrantel Pamoate. Many who have pinworms do not have symptoms. Nevertheless, many will experience itching in and around the rectal opening. The itching may be very annoying and continued scratching can cause an irritation in this area. The itching may be presented at night when sleeping. That is why restless sleep is sometimes a sign of pinworms, especially in children. It is important for you to realize that you should only treat with Pyrantel Pamoate if you have seen and identified the pinworms.

Pinworms look like tiny white threads. The female pinworm is about ½ long (the male pinworm is shorter). They live in the bowel. Usually, at night, the female travels to the rectal opening and lays eggs within the skin folds around the opening. This usually takes place within one to two hours after the child has been put to bed for the night. The sticky gelatin-like substance in which the eggs (they are too small to see) are deposited and the movement of the female pinworm may cause annoying itching and possibly restless sleep. By checking the rectal opening at this time, you can attempt to see the pinworm as described.

The pinworm eggs normally survive for as long as three weeks. In that time, the pinworm egg may hatch and the pinworm will travel back within the rectal opening into the bowel. The pinworm reaches maturity in the bowel within two to six weeks and the life cycle repeats itself.

Scratching will cause pinworm eggs to stick to the fingers. Reinfection will result if the fingers are placed in the mouth. The eggs, which are too small to see, contaminate whatever they come in contact with: bed clothes, underwear, toys, hands, and food touched by contaminated hands. Even eggs floating in the air can be swallowed and cause infection. Eggs deposited in the environment, as stated above, can survive for as long as three weeks. Pinworms are highly contagious. Even the cleanest and most careful people can get them.

After treatment with Pyrantel Pamoate, there are some rules to follow to try to prevent spreading to others and reinfection:

 Wash hands and fingernails with soap often during the day, especially before eating and after using the toilet.

- Wear tight underpants both day and night. Change them daily.
- For several days after treatment, clean the bedroom floor by vacuuming or damp mopping. Avoid dry sweeping that may stir up dust.
- After treatment, wash bed linens and night clothes (don't shake them).
- Keep the toilet seats clean.

Columbia Laboratories

944 Nandino Blvd.

Lexington, KY 40511

NDC: 62337-415-16

### **PYRANTEL PAMOATE SUSPENSION**

(Pyrantel base: 50 mg / mL)

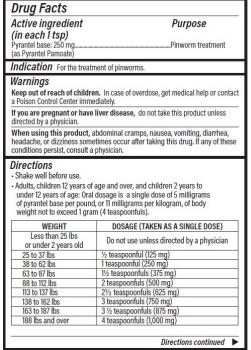
### PINWORM TREATMENT

### COLOMBIA LABORATORIES

944 Nandino Blvd.

Lexington, KY 40511

### NET CONTENTS:16 FL OZ (473.2 mL)



NDC: 62337-415-16

# PYRANTEL PAMOATE SUSPENSION

(Pyrantel base: 50 mg / mL)

PINWORM TREATMENT



Net Contents: 16 fl oz (473.2 mL)

### **Drug Facts** (continued)

### Directions (continued)

- Dosage information: Each 5 mL (1 teaspoonful) of Pyrantel Pamoate Suspension contains the equivalent of 250 mg of pyantel base.
   Read package insert carefully before taking this medication.
- Take only according to directions and do not exceed the recommended dosage unless directed by a physician.
- Medication should only be taken one time as a single dose; do not repeat treatment unless directed by a physician.
- When one individual in a household has pinworms, the entire household should be treated unless otherwise advised. See Warnings.
   If any worms other than pinworms are present before or after treatment, consult a physician.
- If any symptoms or pinworms are still present after treatment, consult a physician.
- This product can be taken any time of day, with or without meals. It may be taken alone or with milk or fruit juice.
- Use of a laxative is not necessary prior to, during, or after medication

### Other information Recommended storage:

 Recommended storage: Store at temperature between 15°C – 30°C (59°F – 86°F).

### Inactive ingredients

Citric Acid, Potassium Sorbate, Purified Water, USP, Sodium Benzoate, Sucrose, Vanilla Flavor, and Xanthan Gum

Questions? Call 859-254-1221 or toll-free 800-621-8829

DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING

1tem No. 09072 26087 09072

L6365-0823

NDC: 62337-415-32

### PYRANTEL PAMOATE SUSPENSION

(Pyrantel base: 50 mg / mL)

### PINWORM TREATMENT

### COLOMBIA LABORATORIES

944 Nandino Blvd.

### NET CONTENTS:32 FL OZ (946.4 mL)

Drug Facts	
Active ingredient	Purpose
(in each 1 tsp) Pyrantel base: 250 mg	Pinworm treatment
(as Pyrantel Pamoate)	

Indication For the treatment of pinworms.

#### Warning

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center immediately.

If you are pregnant or have liver disease,  $\,$  do not take this product unless directed by a physician.

When using this product, abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these conditions persist, consult a physician.

#### **Directions**

- Shake well before use.
- Adults, children 12 years of age and over, and children 2 years to under 12 years of age: Oral dosage is a single dose of 5 milligrams of pyrantel base per pound, or 11 milligrams per kilogram, of body weight not to exceed 1 gram (4 teaspoonfuls).

WEIGHT	DOSAGE (TAKEN AS A SINGLE DOSE)		
Less than 25 lbs or under 2 years old	Do not use unless directed by a physician		
25 to 37 lbs	½ teaspoonful (125 mg)		
38 to 62 lbs	1 teaspoonful (250 mg)		
63 to 87 lbs	1½ teaspoonfuls (375 mg)		
88 to 112 lbs	2 teaspoonfuls (500 mg)		
113 to 137 lbs	2½ teaspoonfuls (625 mg)		
138 to 162 lbs	3 teaspoonfuls (750 mg)		
163 to 187 lbs	3 ½ teaspoonfuls (875 mg)		
188 lbs and over	4 teaspoonfuls (1,000 mg)		

- Dosage information: Each 5 mL (1 teaspoonful) of Pyrantel Pamoate Suspension contains the equivalent of 250 mg of pyantel base.
- Read package insert carefully before taking this medication.

Directions continued

**ORAL** 

NDC: 62337-415-32



# PYRANTEL PAMOATE SUSPENSION

(Pyrantel base: 50 mg / mL)

### PINWORM TREATMENT

### Drug Facts (continued)

### Directions (continued)

- Take only according to directions and do not exceed the recommended dosage unless directed by a physician.
- Medication should only be taken one time as a single dose; do not repeat treatment unless directed by a physician.
- When one individual in a household has pinworms, the entire household should be treated unless otherwise advised. See Warnings.
- If any worms other than pinworms are present before or after treatment, consult a physician.
- If any spring consult a physician.

  If any spring the strict real property of the strict real physician is a strict real physician and the strict real physician is a strict real physician and the strict real physician is a strict real physician and the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real physician is a strict real physician in the strict real
- a physician.

  This product can be taken any time of day, with or without meals. It
- may be taken alone or with milk or fruit juice.

  Use of a laxative is not necessary prior to, during, or after medication.

### Other information

 Recommended storage: Store at temperature between 15°C – 30°C (59°F – 86°F).

### Inactive ingredients

Citric Acid, Potassium Sorbate, Purified Water, USP, Sodium Benzoate, Sucrose, Vanilla Flavor, and Xanthan Gum

Questions? Call 800-525-2022 or toll-free 800-621-8829.

DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING



Net Contents: 32 fl oz (946.4 mL)

Item No. 09073

L6366-0823

### **PYRANTEL PAMOATE**

pinwormtreatment suspension

### **Product Information**

**Route of Administration** 

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62337-415
--------------	----------------	--------------------	---------------

### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	50 mg in 1 mL

# Inactive Ingredients Ingredient Name Strength CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) SODIUM BENZOATE (UNII: 0J245FE5EU) SUCROSE (UNII: C151H8M554) VANILLA (UNII: Q74T35078H) WATER (UNII: 059QF0KO0R) XANTHAN GUM (UNII: TTV12P4NEE)

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:62337- 415-16	473.2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/17/2012			
2	NDC:62337- 415-32	946.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/17/2012			

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date					
OTC Monograph Drug	M024	10/17/2012			

### Labeler - Neogen Corporation dba Columbia Laboratories (795452556)

Establishment				
Name	Address	ID/FEI	Business Operations	
Neogen Corporation - Mercer Rd.		042125879	analysis(62337-415), label(62337-415), manufacture(62337-415)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
minsheng group shaoxing pharmaceutical co. Itd		544607919	api manufacture(62337-415)	

Revised: 10/2023 Neogen Corporation dba Columbia Laboratories