# PYRANTEL PAMOATE- pinwormtreatment suspension Neogen Corporation dba Columbia Laboratories

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# Active Ingredients (in each 1 tsp)

Pyrantel base: 250 mg (as Pyrantel Pamoate)

# Purpose

Pinworm treatment

### Use

for the treatment of pinworms.

# **Warnings**

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**Keep out of reach of children.** In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

**If pregnant or if you 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 may occur.

**Stop use and ask a doctor if** abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness persist.

# Directions

- Shake well before use.
- 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.
- This product can be taken any time of day, with or without meals. It may be taken alone or with milk or juice.
- Use of a laxative is not necessary prior to, during, or after medication.
- 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).

- 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.
- 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.

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)

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)

# Other information

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

# **Inactive Ingredients**

BHT, Citric Acid, Flavor, Potassium Sorbate, Purified water, Sodium Benzoate, Sucrose, 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

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38 to 62 Pounds......1 teaspoonful (250 mg)

88 to 112 Pounds......2 teaspoonfuls (500 mg)

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# **Inactive Ingredients**

BHT, Citric Acid, Potassium Sorbate, Purified water, Sodium Benzoate, Sucrose, Xanthan gum *Questions?* Call 859/254-1221 or toll-free 800/621-8829.

Manufactured for: Columbia Laboratories 944 Nandino Blvd, Lexington, KY 40511 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.

NDC: 62337-415-16

PYRANTEL PAMOATE SUSPENSION

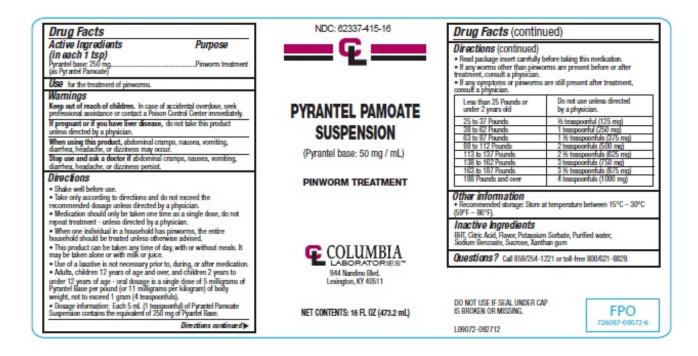
(Pyrantel base: 50 mg / mL)
PINWORM TREATMENT

**COLUMBIA LABORATORIES** 

944 Nandino Blvd.

Lexington, KY 40511

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



NDC: 62337-415-32

# PYRANTEL PAMOATE SUSPENSION

(Pyrantel base: 50 mg / mL)

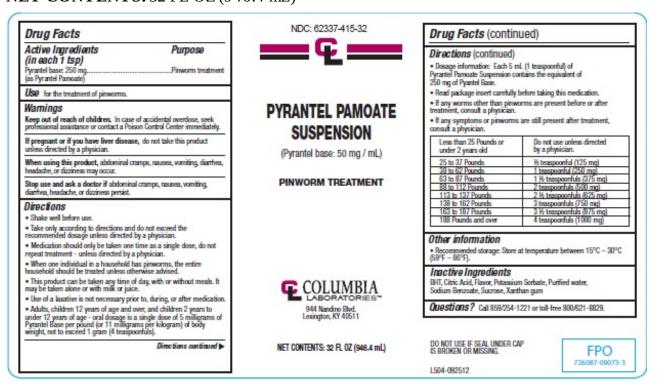
### PINWORM TREATMENT

### **COLUMBIA LABORATORIES**

944 Nandino Blvd.

Lexington, KY 40511

NET CONTENTS: 32 FL OZ (946.4 mL)



# PYRANTEL PAMOATE

pinwormtreatment suspension

# **Product Information**

WATER (UNII: 059QF0KO0R)

XANTHAN GUM (UNII: TTV12P4NEE)

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62337-415
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Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Active ingredient/Active wholety		
Ingredient Name	Basis of Strength	Strength
PYRANTEL PAMO ATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7)	PYRANTEL	50 mg in 1 mL

# Inactive Ingredients Ingredient Name Strength BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K) CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP) POTASSIUM SORBATE (UNII: 1VPU26 JZZ4) SODIUM BENZO ATE (UNII: OJ245FE5EU) SUCRO SE (UNII: C151H8 M554) VANILLA (UNII: Q74T35078 H)

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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part357B	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	Business Operations
minsheng group shaoxing pharmaceutical co. ltd		544607919	api manufacture(62337-415)

Revised: 3/2019

Neogen Corporation dba Columbia Laboratories