

**PYRANTEL PAMOATE- pinworm treatment 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***

***Warnings***

**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 use 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)

***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**

***Drug Facts***

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**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  $\frac{1}{2}$  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)**

**Drug Facts****Active Ingredients**

(in each 1 tsp)

Pyrantel base: 250 mg

(as Pyrantel Pamoate)

**Purpose**

Pinworm treatment

**Use** for the treatment of pinworms.**Warnings****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**

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*Directions continued* ▶

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)**

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**Other information**

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**Questions?**

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L09072-092712

**FPO**

726087-09072-6

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)

**Drug Facts****Active Ingredients**

(in each 1 tsp)

Pyrantel base: 250 mg

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Pinworm treatment

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*Directions continued* ▶

NDC: 62337-415-32

**PYRANTEL PAMOATE  
SUSPENSION**

(Pyrantel base: 50 mg / mL)

**PINWORM TREATMENT**

NET CONTENTS: 32 FL OZ (946.4 mL)

**Drug Facts (continued)****Directions (continued)**

• Dosage information: Each 5 mL (1 teaspoonful) of Pyrantel Pamoate Suspension contains the equivalent of 250 mg of Pyrantel Base.

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L504-092512

**FPO**

726087-09073-3

# PYRANTEL PAMOATE

pinwormtreatment suspension

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
VANILLA (UNII: Q74T35078H)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## 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