CESAR CASTILLO
LLC
Established 1942

PRODUCT NOTIFICATION

Pyrantel Pamoate Suspension (Pyrantel base: 50mg / ml)
16 fl oz (473.2 mL) and 32 fl oz (946.4 mL)

See full document included for detailed information.

June 12, 2024

Dear Customer,

We have received a Product Notification from Neogen. You have been contacted because our records indicate that you may have received the affected lot that Cesar Castillo LLC distributed.

Please note this is not a Recall.

In case you have the affected lot on hand, please refer to instructions on Neogen Product Notification attached.

Luis R. Ramírez
Animal Health Manager
787-999-1616 Ext 1251
Email: lramirez@cesarcastillo.com

Product Notification

Columbia Laboratories, Pyrantel Pamoate Suspension (Pyrantel base: 50mg / ml)
16 fl oz (473.2 mL) and 32 fl oz (946.4 mL)

Lot Number: 10143, Expiration Date: 07/31/2024

Neogen Corporation
1847 Mercer Rd.
Lexington, KY 40511

Dear CESAR CASTILLO LLC,

This is to notify you that the above product, lot number 10143, expiration date 07/31/2024, may have units that have fallen out of suspension. While we have not been able to verify this, all controlled samples were within specifications, we are offering to replace any units in stock at your distribution center. If these product lots have been further distributed, please feel free to extend this offer to your customers.

See enclosed product labels.

Neogen Corporation would like to remind customers that Pyrantel Pamoate Suspension is an Anthelmintic, Human OTC Drug registered with the FDA for over-the-counter human use. Extra label Drug Use (ELDU) of Pyrantel Pamoate Suspension in animals is permitted in compliance with the Animal Medical Drug Use Clarification Act (AMDUCA) only by or on the order of Veterinarians within the context of a valid Veterinarian-Client-Patient Relationship (VCPR).

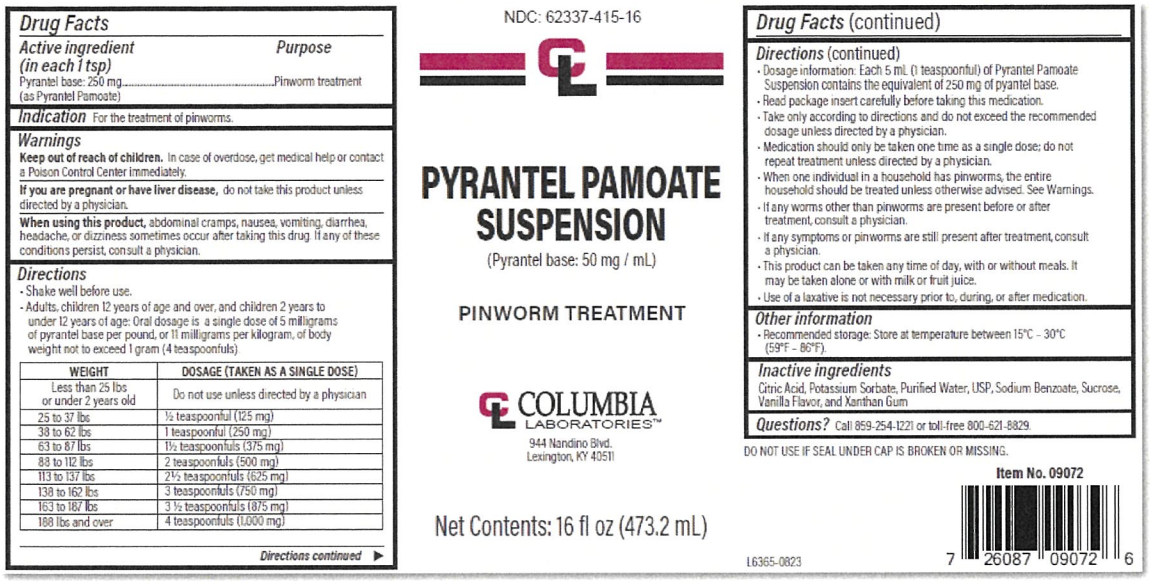
Consumers with questions regarding this notification or with product inventory of the affected lot number as listed above should contact Neogen Customer Service Monday through Friday, 8AM-5PM EDT at 859-254-1221 or Alberto Dominguez via email at adominguez@neogen.com for return shipping instructions.

Katherine A. Raney

Katherine A. Raney
Regulatory Specialist
Neogen Corporation

Columbia Laboratories, Pyrantel Pamoate Suspension (Pyrantel base: (50mg / mL)

	16 fl oz (473.2 mL)	32 fl oz (946.4 mL)
NDC	62337-415-16	62337-415-32
UPC Codes	726087090726	726087090733



Drug Facts

Active ingredient (in each 1 tsp) — **Purpose**
Pyrantel base: 250 mg (as Pyrantel Pamoate) — 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 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)

Directions continued ▶

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 (continued)

Directions (continued)
- 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. 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: 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

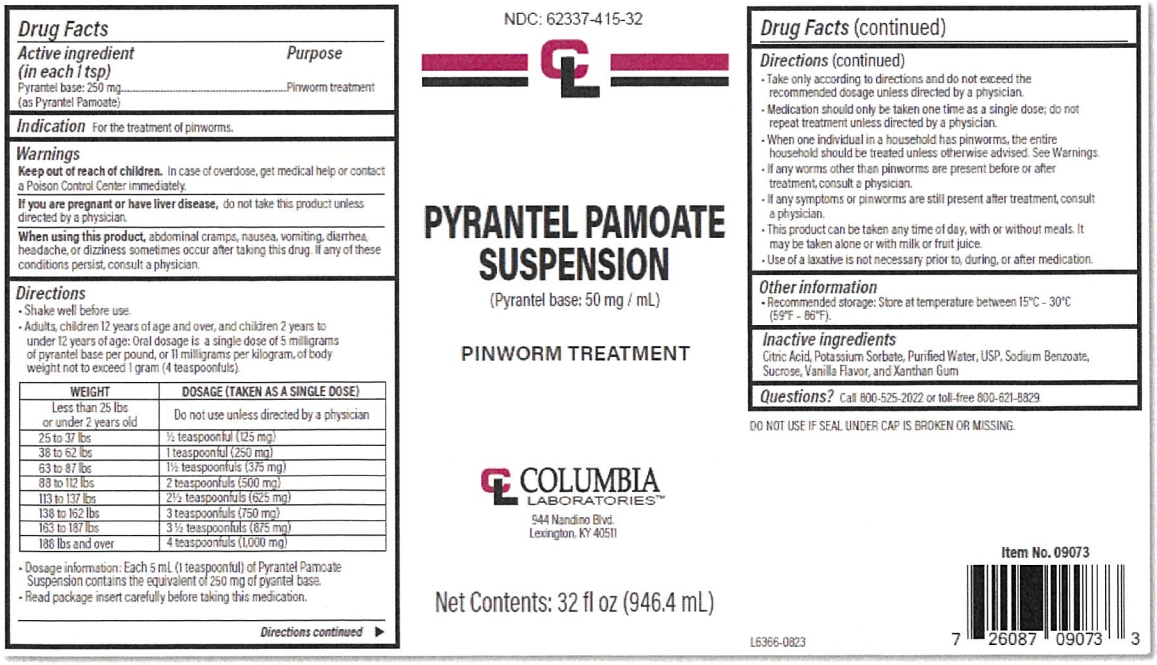
Questions? Call 859-254-1221 or toll-free 800-621-8829.

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

Item No. 09072

L6365-0823

7 26087 09072 6



Drug Facts

Active ingredient (in each 1 tsp) — **Purpose**
Pyrantel base: 250 mg (as Pyrantel Pamoate) — 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 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 pyrantel base.
- Read package insert carefully before taking this medication.

Directions continued ▶

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 (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 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 800-525-2022 or toll-free 800-621-8829.

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

Item No. 09073

L6366-0823

7 26087 09073 3