

PYRANTEL PAMOATE- pyrantel pamoate suspension

Jefferson Labs

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.

ORAL-PRO™

Pyrantel Pamoate Oral Suspension

Pinworm Treatment

Pyrantel Pamoate Oral Suspension is used for the treatment of pinworms.

Drug Facts

Active Ingredient

Each 1 mL contains:

Pyrantel base

(as Pyrantel Pamoate) 50 mg

Purpose

Pinworm
treatment

Uses

- For pinworm treatment

Warnings

- Abdominal cramps, nausea, vomiting, diarrhea, headache or dizziness sometimes occur after taking this drug. If any of these conditions persist, consult a physician.
- Keep this and all medications out of reach of children.
- In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Do not use

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

When using this product

- Shake well before use.

Directions

- Adults and children 2 years to 12 years of age may take this product. Take the dosage in Table I according to the body weight of the individual treated. Do not exceed 4 teaspoonful (20.0 mL) of Pyrantel Pamoate Oral Suspension.
- Carefully read additional product information (located on the inside of label) before using 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 juice. Use of a laxative is not necessary prior to, during or after medication.

Dosage Information

Each mL of Pyrantel Pamoate Oral Suspension contains the equivalent of 50 mg of Pyrantel Base (as Pyrantel Pamoate).

**Table 1.
Pyrantel Pamoate Oral Suspension Dosage Guide**

Less than 25 lbs. (11 Kg) or under 2 years old	Do not use unless directed by a physician
25-37 lbs. (11-16 kg)	1/2 teaspoonful (2.5 mL)
38-62 lbs. (17-28 kg)	1 teaspoonful (5.0 mL)
63-87 lbs. (29-39 kg)	1 1/2 teaspoonful (7.5 mL)
88-112 lbs. (40-50 kg)	2 teaspoonful (10.0 mL)
113-137 lbs. (51-62 kg)	2 1/2 teaspoonful (12.5 mL)
138-162 lbs. (63-73 kg)	3 teaspoonful (15.0 mL)
163-187 lbs. (74-84 kg)	3 1/2 teaspoonful (17.5 mL)
188 lbs. (85 kg and over)	4 teaspoonful (20.0 mL)

Other Information

Each teaspoonful contains: Potassium 5 mg.

Store at 20°–25° C (68°–77° F). Excursions permitted between 15°–30° C (59°–86° F). Do not freeze.

Inactive Ingredients

Citric acid, potassium sorbate, purified water, glycerin, sodium benzoate, sucralose, vanilla custard flavor, xanthan gum.

Questions? 1-888-215-1256

PEEL BACK AT CORNER FOR IMPORTANT PRODUCT INFORMATION

MANUFACTURED IN THE USA



Do not use if the seal is open or broken.

REORDER NO: 21013

Manufactured by:

Jefferson Labs

NORTHFIELD, MINNESOTA 55057

888-215-1256

IN 50-1419 07/2015



Keep Out of Reach of Children

PRINCIPAL DISPLAY PANEL - 946 mL Bottle Label

NDC 51072-088-00

ORAL-PRO®

Pyrantel Pamoate

Oral Suspension

Pinworm Treatment

50 mg/mL Pyrantel Base

Pharmacy Bulk Pack

Keep Out of Reach of Children

32 fl. oz. (946 mL)

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MANUFACTURED BY:
Jefferson Labs
NORTHFIELD, MINNESOTA 55057
888-215-1256
IN 50-1419 01/2018

51072-088-00

MANUFACTURED IN THE USA

TAKE TIME OBSERVE LABEL DIRECTIONS

Pyrantel Pamoate Oral Suspension is used for the treatment of pinworms.

Drug Facts	
Active Ingredient	Purpose
Pyrantel base Pinworm treatment	(as Pyrantel Pamoate) 50 mg
Uses	
■ For pinworm treatment	
Warnings	
■ Abdominal cramps, nausea, vomiting, diarrhea, headache or dizziness sometimes occur after taking this drug. If any of these conditions persist, consult a physician.	
■ Keep this and all medications out of reach of children.	
■ In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.	
Do not use	
■ If you are pregnant or have liver disease, do not take this product unless directed by a physician.	
When using this product	
■ Shake well before use.	
Directions	
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Drug Facts (continued)

Directions (continued)
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Citric acid, potassium sorbate, purified water, glycerin, sodium benzoate, sucralose, vanilla custard flavor, xanthan gum.

Questions? 1-888-215-1258

NDC 51072-088-00

Pyrantel Pamoate Oral Suspension

Pinworm Treatment
50 mg/mL Pyrantel Base

Pharmacy Bulk Pack

Keep Out of Reach of Children

32 fl. oz. (946 mL)

PYRANTEL PAMOATE

pyrantel pamoate suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 72-088
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	VANILLA (custard)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-088-00	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2015	
2	NDC:51072-088-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part357B	11/21/2015	

Labeler - Jefferson Labs (832848639)

Establishment

Name	Address	ID/FEI	Business Operations
Jefferson Labs		832848639	manufacture(51072-088)

Revised: 5/2018

Jefferson Labs