

PYRANTEL PAMOATE- pyrantel pamoate suspension
Jefferson Labs

ORAL-PRO™
Pyrantel Pamoate Oral Suspension
Pinworm Treatment

50 mg/mL Pyrantel Base

Pharmacy Bulk Pack

Drug Facts

| <i>Active Ingredient</i> | <i>Purpose</i> |
|---|-----------------------|
| Each 1 mL contains: Pyrantel base (as Pyrantel Pamoate) 50 mg | Pinworm treatment |

Indications

- For the treatment of pinworms.

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

Pyrantel Pamoate Oral Suspension Dosage Guide

| Weight | Dosage (taken as a single dose) |
|--|---|
| Less than 25 pounds or under 2 years old | Do not use unless directed by a physician |
| 25 to 37 pounds | 1/2 teaspoonful (125 mg) |
| 38 to 62 pounds | 1 teaspoonful (250 mg) |
| 63 to 87 pounds | 1 1/2 teaspoonfuls (375 mg) |
| 88 to 112 pounds | 2 teaspoonfuls (500 mg) |
| 113 to 137 pounds | 2 1/2 teaspoonfuls (625 mg) |
| 138 to 162 pounds | 3 teaspoonfuls (750 mg) |
| 163 to 187 pounds | 3 1/2 teaspoonfuls (875 mg) |
| 188 pounds and over | 4 teaspoonfuls (1,000 mg) |

Other Information

Each teaspoonful contains: Potassium 5 mg.

Store upright 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
1-888-215-1256
 IN 50-1419 03/2021



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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TAKE TIME OBSERVE LABEL DIRECTIONS

3 51072-08800 8

Drug Facts

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Drug Facts (continued)

Directions (continued)
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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)

PYRANTEL PAMOATE

pyrantel pamoate suspension

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51072-088

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: 059QF0KO0R) | |

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:51072-088-02 | 946 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/19/2022 | |
| 3 | NDC:51072-088-01 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/28/2017 | |
| 4 | NDC:51072-088-03 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/19/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M024 | 11/21/2015 | |

Labeler - Jefferson Labs (832848639)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Revised: 12/2023

Jefferson Labs