

PINWORM MEDICINE- pyrantal pamoate suspension
Proficient Rx LP

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.

Drug Facts

Active ingredient (in each mL)

Pyrantel Pamoate 144mg/mL (the equivalent of 50mg pyrantel base)

Purpose

Anthelmintic

Uses for the treatment of pinworms

Warnings Do not exceed recommended dosage

Ask a doctor before use if

- you're pregnant
- have liver disease

When using this product abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness sometimes occur after taking this drug. If any of these symptoms persist, consult a doctor.

Keep out of reach of children. In case of overdose get medical help or contact a poison control center right away.

Directions

- **shake well before use**
- **read bottle label and package insert carefully before taking this medication**
- treat the entire household unless otherwise advised
- do not repeat treatment unless directed by a doctor
- 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
- if signs of pinworms persist after treatment, consult a doctor

Weight

Less than 25 lb. or under 2 yrs.old
25-37 lb.
38-62 lb.
63-87 lb.
88-112 lb.
113-137 lb.
138-162 lb.
163-187 lb.
188 lb. and over

Dosage (taken as a single dose)

Do not use unless directed by a doctor
1/2 teaspoonful
1 teaspoonful
1 1/2 teaspoonfuls
2 teaspoonfuls
2 1/2 teaspoonfuls
3 teaspoonfuls
3 1/2 teaspoonfuls
4 teaspoonfuls

Inactive ingredients

banana flavor, citric acid, glycerin, lecithin, magnesium aluminum silicate, methylcellulose, povidone,

simethicone, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, and water



NDC 63187-586-30

Lot # 00000
Exp 00/00/00
RX# MASTER

Pinworm Medicine 144mg/mL

1 FL. OZ. (30 mL) Suspension

Each mL contains: Pyrantel Pamoate 144mg/mL (the equivalent of 50mg pyrantel base) Anthelmintic

See Box

Product ID: RP058630

Dist. By: Reese Pharmaceutical 10617 Frank Ave., Cleveland, OH 44106

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320

Pinworm Medicine 144mg/mL
1 FL. OZ. (30 mL) Suspension
Lot # 00000 Rx# MASTER
NDC 63187-586-30 Exp:00/00/00

Pinworm Medicine 144mg/mL
1 FL. OZ. (30 mL) Suspension
Lot # 00000 Rx# MASTER
NDC 63187-586-30 Exp:00/00/00

Pinworm Medicine 144mg/mL
1 FL. OZ. (30 mL) Suspension
Lot # 00000 Rx# MASTER
NDC 63187-586-30 Exp:00/00/00

Pinworm Medicine 144mg/mL
1 FL. OZ. (30 mL) Suspension
Lot # 00000 Rx# MASTER
NDC 63187-586-30 Exp:00/00/00

PINWORM MEDICINE

pyrantel pamoate suspension

Product Information

| | | | |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63187-586(NDC:10956-618) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| PYRANTEL PAMOATE (UNII: 81BK194Z5M) (PYRANTEL - UNII:4QIH0N49E7) | PYRANTEL | 144 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) | |
| METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J) | |
| POVIDONES (UNII: FZ989GH94E) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0K00R) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | BANANA | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63187-586-30 | 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part357B | 01/01/2007 | |

Labeler - Proficient Rx LP (079196022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|---------------------|
| Proficient Rx LP | | 079502574 | RELABEL(63187-586) |

Revised: 11/2015

Proficient Rx LP