

**LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride suspension**  
**Precision Dose Inc.**

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**LOPERAMIDE HYDROCHLORIDE**  
**ORAL SUSPENSION**

1 mg/7.5 mL

2 mg/15 mL

Mint Flavor

***For Hospital Use Only***

***Drug Facts***

**Active Ingredient (in each 7.5 mL)**

Loperamide HCl 1 mg

**Purpose**

Anti-diarrheal

**Use**

controls symptoms of diarrhea, including Travelers' Diarrhea

**Warnings**

**Allergy alert**

Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

**Do not use** if you have bloody or black stool

**Ask a doctor before use if you have**

- fever
- mucus in the stool
- a history of liver disease

**Ask a doctor or pharmacist before use if you are** taking antibiotics

**When using this product**

- tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

**Stop use and ask a doctor if**

- symptoms get worse
- diarrhea lasts for more than 2 days
- you get abdominal swelling or bulging.

These may be signs of a serious condition.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- shake well before using
- use as directed per healthcare professional

**Other Information**

- **each 30 mL (6 tsp) contains:** sodium 13 mg
- store between 20-25°C (68-77°F)
- See individual label or shipper label for lot number and expiration date.

**Inactive ingredients**

anhydrous citric acid, carboxymethylcellulose sodium, D&C yellow no. 10, FD&C blue no. 1, glycerin, microcrystalline cellulose, natural and artificial mint flavor, propylene glycol, purified water, simethicone, sodium benzoate, sucralose, titanium dioxide, xanthan gum

**Gluten Free****How Supplied**

NDC 68094-107-62

7.5 mL per unit dose cup

Thirty (30) cups per shipper

NDC 68094-108-62

15 mL per unit dose cup

Thirty (30) cups per shipper

Manufactured By:

Perrigo Company

515 Eastern Avenue

Allegan, MI 49010

Packaged By:

Precision Dose, Inc.

722 Progressive Lane

South Beloit, IL 61080

LI911

Rev. 04/13

**PRINCIPAL DISPLAY PANEL - 7.5 mL Cup Label**

NDC 68094-107-59

**PrecisionDose™**

**LOPERAMIDE Hydrochloride**

**Oral Suspension**

**1 mg/7.5 mL**

Delivers 7.5 mL Shake Well

Gluten free Contains 3 mg Sodium

Store at 20°-25°C (68°-77°F)

Pkg. By: Precision Dose, Inc.  
S. Beloit, IL 61080



## LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride suspension

### Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68094-107(NDC:0113-0645) |
| <b>Route of Administration</b> | ORAL           |                           |                              |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength        | Strength       |
|--|--------------------------|----------------|
| Loperamide Hydrochloride (UNII: 77T135393C) (Loperamide - UNII:6X9OC3H4II) | Loperamide Hydrochloride | 1 mg in 7.5 mL |

### Inactive Ingredients

| Ingredient Name                          | Strength |
|--|----------|
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) |          |

|  |  |
|--|--|
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) |  |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)             |  |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD)               |  |
| GLYCERIN (UNII: PDC6A3C0OX)                      |  |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)   |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)              |  |
| WATER (UNII: 059QF0K00R)                         |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)               |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                     |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)              |  |
| XANTHAN GUM (UNII: TTV12P4NEE)                   |  |

### Product Characteristics

|          |       |              |  |
|----------|-------|--------------|--|
| Color    | GREEN | Score        |  |
| Shape    |       | Size         |  |
| Flavor   | MINT  | Imprint Code |  |
| Contains |       |              |  |

### Packaging

| # | Item Code        | Package Description        | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:68094-107-62 | 3 in 1 CASE                |                      |                    |
| 1 |                  | 10 in 1 TRAY               |                      |                    |
| 1 | NDC:68094-107-59 | 7.5 mL in 1 CUP, UNIT-DOSE |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA               | ANDA091292                               | 02/26/2014           |                    |

**Labeler** - Precision Dose Inc. (035886746)