

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride suspension
Precision Dose Inc.

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68094-107(NDC:0113-0645)
Route of Administration	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)