LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride solution
Precision Dose, Inc.
Reference Label Set Id: ae8237f0-95a6-4163-b476-25c0509ef151

Loperamide Hydrochloride

Mint Flavor

1 mg/7.5 mL 2 mg/15 mL

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

Read complete directions and warnings before using.

Warnings

Allergy alert

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

Heart alert

Taking more than directed can cause serious heart problems or death

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

- **Use as directed per healthcare professional.**
- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- shake well before using
- mL = milliliter

adults and children 12 years and over	30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours
children 9-11 years (60-95 lbs)	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours
children 6-8 years (48-59 lbs)	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 30 mL in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- **each 30 mL contains:** sodium 15 mg
- store between 20-25°C (68-77°F)

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 68094-029-62
7.5 mL per unit dose cup
Thirty (30) cups per shipper

NDC 68094-129-62
15 mL per unit dose cup
Thirty (30) cups per shipper

Distributed By
Perrigo Company
Allegan, MI 49010

Packaged By
Precision Dose, Inc.
South Beloit, IL 61080

For inquiries call Precision Dose, Inc. at 1-800-397-9228 or email druginfo@precisiondose.com

LI1251 Rev. 04/22

PRINCIPAL DISPLAY PANEL - 2 mg/15 mL Cup Lid Label

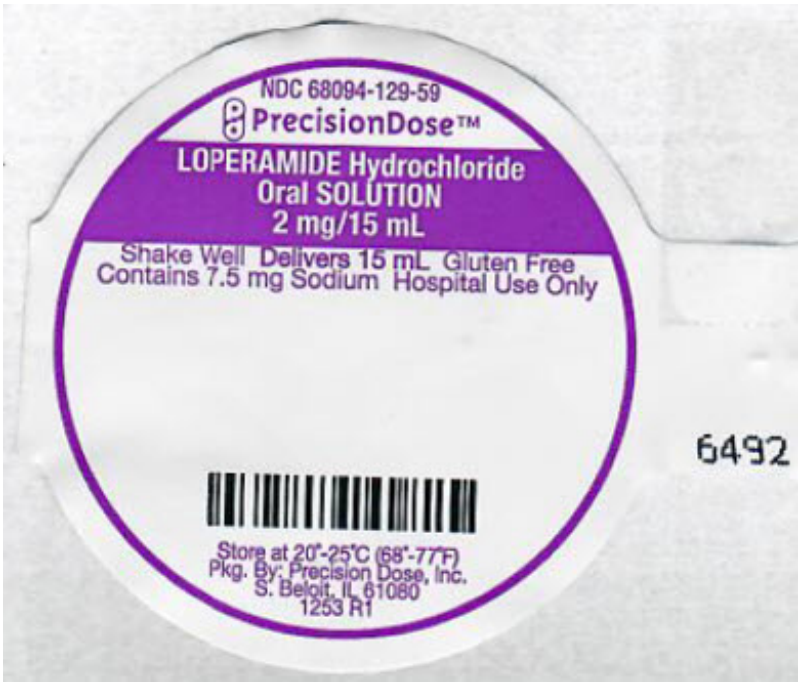
NDC 68094-129-59

PrecisionDose™

LOPERAMIDE Hydrochloride
Oral SOLUTION
2 mg/15 mL

Shake Well Delivers 15 mL Gluten Free
Contains 7.5 mg Sodium Hospital Use Only

Store at 20°-25°C (68°-77°F)
Pkg. By: Precision Dose, Inc.
S. Beloit, IL 61080
1253 R1



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68094-129(NDC:0113-1645)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Loperamide Hydrochloride (UNII: 77TI35393C) (Loperamide - UNII:6X9OC3H4II)	Loperamide Hydrochloride	1 mg in 7.5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
carboxymethylcellulose sodium, unspecified (UNII: K679OBS311)	
D&C Yellow No. 10 (UNII: 35SW5USQ3G)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Glycerin (UNII: PDC6A3C0OX)	
Microcrystalline cellulose (UNII: OP1R32D61U)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sucralose (UNII: 96K6UQ3ZD4)	
titanium dioxide (UNII: 15FIX9V2JP)	
xanthan gum (UNII: TTV12P4NEE)	
dimethicone (UNII: 92RU3N3Y1O)	

silicon dioxide (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	GREEN (opaque, viscous)	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68094-129-62	3 in 1 CASE	05/18/2020	
1		10 in 1 TRAY		
1	NDC:68094-129-59	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	05/18/2020	

Labeler - Precision Dose, Inc. (035886746)

Revised: 6/2023 Precision Dose, Inc.