LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution Rite Aid Corporation

Rite Aid Corporation Loperamide Hydrochloride 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

Heart alert: Taking more than directed can cause serious heart problems or death

Do not use

Ask a doctor before use if you have

- fever
- mucus in the stool
- a history of liver disease
- a history of abnormal heart rhythm

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Loperamide may interact with certain prescription drugs.

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
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- shake well before using
- use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.
- mL = milliliter

	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

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Imodium® A-D

LOPERAMIDE HYDROCHLORIDE Oral Solution, 1 mg per 7.5 mL

ANTI-DIARRHEAL

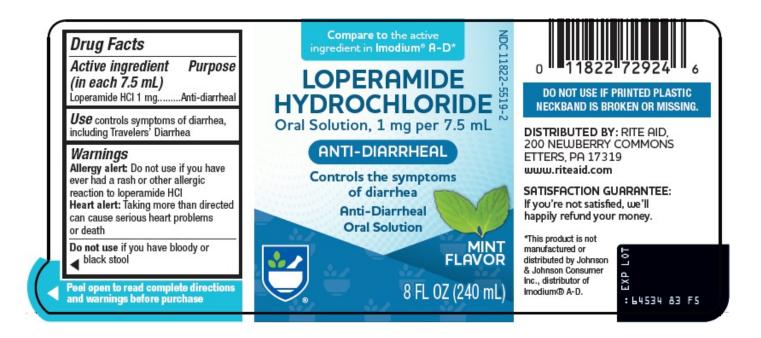
Controls the symptoms of diarrhea

Anti-Diarrheal

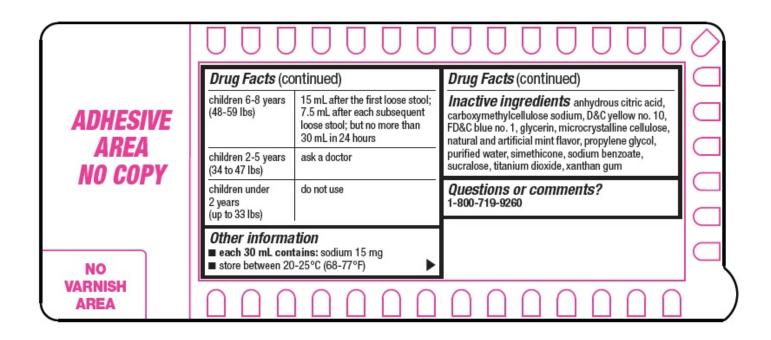
Oral Solution

MINT FLAVOR

8 FL OZ (240 mL)



Drug Facts (continued) Drug Facts (continued) Ask a doctor before use if you have Directions ■ fever ■ mucus in the stool ■ a history of liver disease ■ drink plenty of clear fluids to help prevent a history of abnormal heart rhythm dehydration caused by diarrhea find right dose on chart. If possible, use weight to Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with dose; otherwise use age. shake well before using certain prescription drugs. ■ use only enclosed dosing cup specifically designed When using this product tiredness, drowsiness or for use with this product. Do not use any other dizziness may occur. Be careful when driving or operating dosing device. machinery. ■ mL = milliliter NO COPY Stop use and ask a doctor if symptoms get worse adults and children 30 mL after the first loose stool: diarrhea lasts for more than 2 days 12 years and over 15 mL after each subsequent you get abdominal swelling or bulging. loose stool; but no more than These may be signs of a serious condition. 60 mL in 24 hours If pregnant or breast-feeding, ask a health professional 15 mL after the first loose stool: children 9-11 years before use. (60-95 lbs) 7.5 mL after each subsequent Keep out of reach of children. In case of overdose, get loose stool; but no more than medical help or contact a Poison Control Center right 45 mL in 24 hours away. (1-800-222-1222)



LOPERAMIDE HYDROCHLORIDE

loperamide hcl solution

Droduct	Information
FIUUULL	IIII OI III a LIVII

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-5519

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

LOPERAMIDE | LOPERAMIDE

LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - LOPERAMIDE HYDROCHLORIDE 1 mg in 7.5 mL

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Inactive Ingredients

DIMETHICONE (UNII: 92RU3N3Y1O)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
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)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11822- 5519-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2018	08/30/2024	
2	NDC:11822- 5519-2	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2018		
3	NDC:11822- 5519-3	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020	03/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	06/18/2018	

Labeler - Rite Aid Corporation (014578892)

Revised: 6/2024 Rite Aid Corporation