

**LEADER ANTI DIARRHEAL- loperamide hcl solution**  
**Cardinal Health 110, LLC. dba Leader**

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**Cardinal Health Anti-Diarrheal 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**

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
- 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

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

## Questions or comments?

1-800-719-9260

**Package/Label Principal Display Panel**

Anti-Diarrheal

Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL

Anti-Diarrheal

Mint Flavor

COMPARE TO IMODIUM® A-D active ingredient

Controls the Symptoms of Diarrhea

100% Money Back Guarantee

Anti-Diarrheal Oral Solution

SEE NEW WARNING AND DIRECTIONS

4 FL OZ (120 mL)

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Loperamide HCl 1 mg...Anti-diarrheal

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Peel open to read complete directions and warnings before purchase

LEADER<sup>™</sup>

NDC 70000-0417-1

## Anti-Diarrheal

Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL  
Anti-Diarrheal

**Mint Flavor**  
Controls the Symptoms of Diarrhea

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COMPARE TO IMODIUM<sup>™</sup> A-D active ingredient\*

100% Money Back Guarantee

4 FL OZ (120 mL)

Do not use if printed plastic neckband is broken or missing.

DIST BY CAH  
DUBLIN, OH 43017

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\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Imodium<sup>®</sup> A-D.

CIN 5460472 REV. 1/20



: 64526 E9 F4

### Drug Facts (continued)

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- fever ■ mucus in the stool
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- 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.

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Questions or comments? 1-800-719-9260

# LEADER ANTI DIARRHEAL

loperamide hcl solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0417
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	GREEN (opaque, viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0417-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	07/16/2018	

**Labeler** - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

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