LEADER ANTI DIARRHEAL- loperamide hcl suspension
Cardinal Health

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

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
- find right dose on chart. If possible, use weight to dose; otherwise use age.
- shake well before using
- only use attached measuring cup to dose product

adults and children 12 years and over	30 mL (6 tsp) after the first loose stool; 15 mL (3 tsp) after each subsequent loose stool; but no more than 60 mL (12 tsp) in 24 hours
children 9-11 years (60-95 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 45 mL (9 tsp) in 24 hours
children 6-8 years (48-59 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 30 mL (6 tsp) in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

Other information

- each 30 mL (6 tsp) contains: sodium 15 mg
- store between 20-25°C (68-77°F)
- see side panel 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

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Loperamide Hydrochloride Oral Suspension

Anti-Diarrheal

Mint Flavor

Controls the Symptoms of Diarrhea

COMPARE TO IMODIUM® A-D active ingredient

100% Money Back Guarantee

1 mg Loperamide Hydrochloride per 7.5 mL

8 FL OZ (240 mL)

Drug Facts

Active ingredient (in each 7.5 mL)	Purpose
Loperamide HCl 1 mg	Anti-diarrheal

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PEEL BACK HERE

LEADER™

NDC 70000-0224-1

Loperamide Hydrochloride Oral Suspension

Anti-Diarrheal

Mint Flavor

Controls the Symptoms of Diarrhea

1 mg Loperamide Hydrochloride per 7.5 mL

COMPARE TO IMODIUM® A-D active ingredient*

100% Money Back Guarantee

8 FL OZ (240 mL)

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

Gluten Free

*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Imodium®.

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com
1-800-200-6313

Essential to Care™ since 1979

100% Money Back Guarantee

Return to place of purchase.

CIN 5309760 REV. 12/16

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: 64534 E9 F1

Drug Facts (continued)

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Drug Facts (continued)

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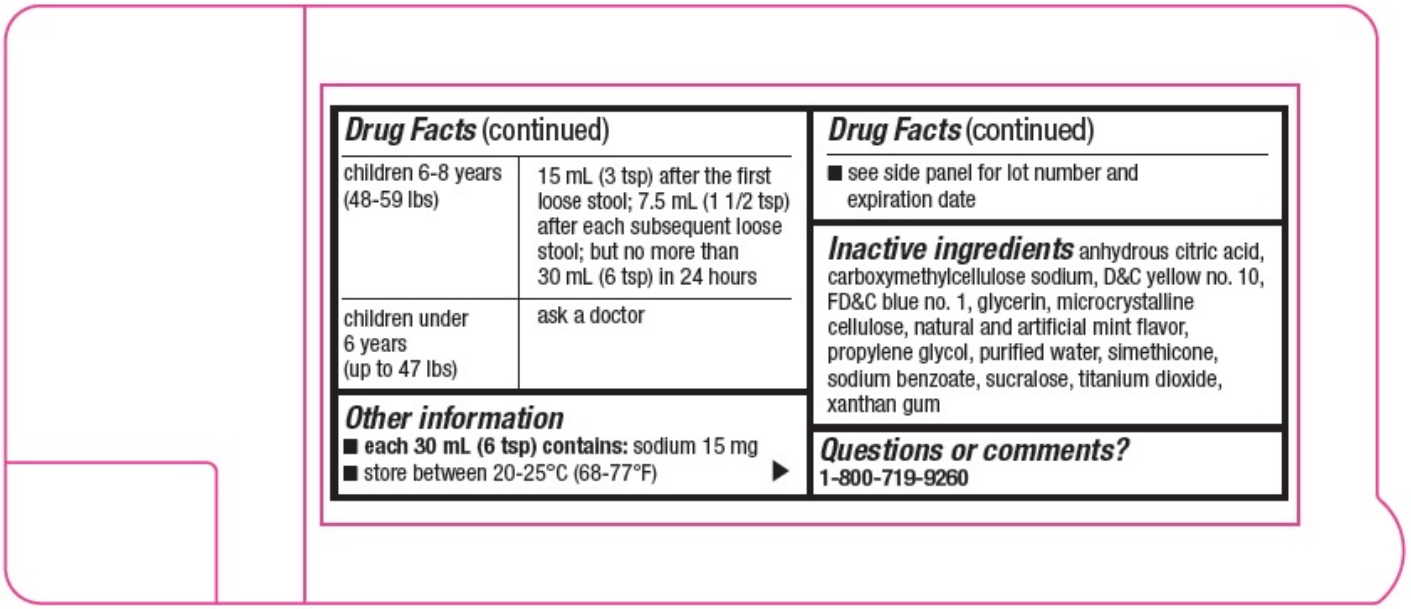

LEADER ANTI DIARRHEAL

loperamide hcl suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0224
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI3539 3C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0224-1	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/19/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	01/19/2017	

Labeler - Cardinal Health (097537435)

Revised: 1/2017 Cardinal Health