

CAREONE DIARRHEA CONTROL- loperamide hcl suspension
American Sales Company

American Sales Company Diarrhea Control 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

Compare to the active ingredient in Imodium® A-D

DIARRHEA CONTROL

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

Controls the symptoms of diarrhea

Mint Flavor

Anti-Diarrheal Oral Solution

See New Warning and Directions

8 FL OZ (240mL)

Drug Facts

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(in each 7.5 mL)

Loperamide HCl 1 mg.....Anti-diarrheal

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

Do not use if you have bloody or black stool

Peel open to read complete directions and warnings before purchase

CAREone™

NDC 41520-767-34

Compare to the active ingredient in Imodium® A-D*

DIARRHEA CONTROL

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

Controls the symptoms of diarrhea

Anti-Diarrheal Oral Solution

See New Warning and Directions

Mint Flavor

8 FL OZ (240mL)

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

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

Gluten Free

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FOODHOLD U.S.A., LLC
LANDOVER, MD 20785
1-877-846-9949
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Quality guaranteed or your money back.



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Drug Facts (continued)

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- 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.

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These may be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

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Drug Facts (continued)

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Drug Facts (continued)

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Questions or comments?

1-800-719-9260

loperamide hcl suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-767
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 FORM (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
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:41520-767-26	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2016	
2	NDC:41520-767-34	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	09/20/2016	

Labeler - American Sales Company (809183973)

Revised: 2/2020

American Sales Company