

CAREONE DIARRHEA CONTROL- loperamide hydrochloride 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 Anti-Diarrheal Oral Solution

For Ages 6 Years And Up

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 Warnings and Directions

4 FL OZ (120mL)

Drug Facts

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(in each 7.5 mL)
Loperamide HCl 1 mg....Anti-diarrheal

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Peel open to read complete directions and warnings before purchase

CAREone®

NDC 41520-841-26

Compare to the active ingredient in Imodium® A-D Anti-Diarrheal Oral Solution*

For Ages 6 Years And Up

DIARRHEA CONTROL

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

Controls the symptoms of diarrhea

Anti-Diarrheal Oral Solution

Mint Flavor

4 FL OZ (120mL)

See New Warning and Directions

Do not use if printed plastic neckband is broken or missing

Gluten Free

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

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Drug Facts (continued)

Do not use if you have bloody or black stool

Ask a doctor before use if you have

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- a history of abnormal heart rhythm

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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
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- 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

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Drug Facts (continued)

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Questions or comments? 1-800-740-0260

CAREONE DIARRHEA CONTROL

loperamide hydrochloride suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-841
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)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-841-26	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	11/23/2016	

Labeler - American Sales Company (809183973)

Revised: 4/2020

American Sales Company