

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

CAREone®

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

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

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Controls the symptoms of diarrhea

Anti-Diarrheal Oral Solution

Mint Flavor

See New Warning and Directions

4 FL OZ (120mL)

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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EXP LOT

: 75626 OF F4

Drug Facts (continued)

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Questions or comments? 1-800-719-9260

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 (UNII: K679OBS311) | |
| 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) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| 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: 7/2025

American Sales Company