

**LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution**  
CVS Pharmacy

-----  
**CVS Pharmacy, Inc. Loperamide Hydrochloride 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<sup>®</sup> A-D

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

4 FL OZ (120 mL)

### Drug Facts

**Active ingredient Purpose**  
(in each 7.5 mL)  
Loperamide HCl 1 mg....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

Peel open to read complete directions and warnings before purchase



Compare to the active ingredient in Imodium® A-D\*  
NDC 69842-191-26

## 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

4 FL OZ (120 mL)



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.

Distributed by: CVS Pharmacy, Inc.  
One CVS Drive, Woonsocket, RI 02895  
© 2019 CVS/pharmacy  
CVS.com® 1-800-SHOP CVS

V-16467

#888495



0

50428 37774 1

: 64526 17 F5

### Drug Facts (continued)

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

ADHESIVE AREA NO COPY

### Drug Facts (continued)

- 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

ADHESIVE AREA NO COPY

# LOPERAMIDE HYDROCHLORIDE

loperamide hcl solution

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-191
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: 059QF0KO0R)	
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:69842-191-26	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2018	
2	NDC:69842-191-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	06/28/2018	

**Labeler** - CVS Pharmacy (062312574)

Revised: 1/2020

CVS Pharmacy