

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride suspension
CVS Pharmacy

CVS Pharmacy, Inc. Loperamide Hydrochloride Oral Suspension 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

Compare to the active ingredient in Imodium® A-D

LOPERAMIDE HYDROCHLORIDE ORAL SUSPENSION

ANTI-DIARRHEAL

Controls the symptoms of diarrhea

4 FL OZ (120 mL)

1 mg Loperamide Hydrochloride per 7.5 mL

Mint Flavor

Drug Facts

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

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Warnings
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Do not use if you have bloody or black stool

PEEL BACK HERE



NDC 59779-645-26
 Compare to the active ingredient in Imodium® A-D*

LOPERAMIDE HYDROCHLORIDE ORAL SUSPENSION ANTI-DIARRHEAL

Controls the symptoms of diarrhea

4 FL OZ (120 mL)
 1 mg Loperamide Hydrochloride per 7.5 mL



Do not use if printed plastic neckband is broken or missing.
 *This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Imodium® A-D.

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Drug Facts (continued)

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

Drug Facts (continued)

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

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Drug Facts (continued)

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Questions or comments?
 1-800-719-9260

LOPERAMIDE HYDROCHLORIDE

loperamide hcl suspension

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:59779-645
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (LOPERAMIDE)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
CARBOXYMETHYLCELLULOSE SODIUM	
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	
GLYCERIN	
CELLULOSE, MICROCRYSTALLINE	
PROPYLENE GLYCOL	
WATER	
SODIUM BENZOATE	
SUCRALOSE	
TITANIUM DIOXIDE	
XANTHAN GUM	

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:59779-645-26	120 mL in 1 BOTTLE		
2	NDC:59779-645-34	237 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	02/28/2012	

