

TOPCARE LOPERAMIDE HYDROCHLORIDE- loperamide hcl suspension
Topco Associates LLC

Topco Associates LLC. 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?

1-888-423-0139

Package/Label Principal Display Panel

MINT FLAVOR

Loperamide Hydrochloride Oral Suspension

ANTI-DIARRHEAL

Controls the symptoms of diarrhea

COMPARE TO IMODIUM® A-D active ingredient

4 FL OZ (120 mL)

1 mg loperamide hydrochloride per 7.5 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

Do not use if you have bloody or black stool

PEEL BACK HERE

NDC 36800-645-26

MINT FLAVOR

Loperamide Hydrochloride Oral Suspension

ANTI-DIARRHEAL

• Controls the symptoms of diarrhea



COMPARE TO IMODIUM® A-D active ingredient*

4 FL OZ (120 mL)

1 mg loperamide hydrochloride per 7.5 mL

TopCare®

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

QUALITY GUARANTEED

GLUTEN FREE

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL
60007
1-888-423-0139
©TOPCO PER1213
topcare@topco.com

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Imodium® A-D.



0 36800 36753 1

: 64526 88 F2

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

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
---------------------------------	---

Drug Facts (continued)

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)

Drug Facts (continued)

■ 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?

1-888-423-0139

TOPCARE LOPERAMIDE HYDROCHLORIDE

loperamide hcl suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-645
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 (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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:36800-645-26	120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	06/05/2012	

Labeler - Topco Associates LLC (006935977)

Revised: 6/2014

Topco Associates LLC