ANTI-DIARRHEAL- loperamide hydrochloride solution Safeway

Better Living Brands Anti-Diarrheal Oral Solution LLC 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	30 mL after the first loose stool; 15 mL after
12 years and over	each subsequent loose stool; but no more
	than 60 mL in 24 hours
children 9-11	15 mL after the first loose stool; 7.5 mL after
years	each subsequent loose stool; but no more
(60-95 lbs)	than 45 mL in 24 hours
children 6-8 years	15 mL after the first loose stool; 7.5 mL after
(48-59 lbs)	each subsequent loose stool; but no more
	than 30 mL in 24 hours
children 2-5 years	ask a doctor
(34 to 47 lbs)	
children under 2	do not use
years	
(up to 33 lbs)	

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

Signature SELECT[™]

COMPARE TO Imodium® A-D active ingredient

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION 1mg per 7.5 mL

ANTI-DIARRHEAL ORAL SOLUTION

MINT FLAVOR

Controls the symptoms of diarrhea

Anti-Diarrheal Oral Solution

LOVE IT OR IT'S ON US

SEE NEW WARNING AND DIRECTIONS

8 FL OZ (240 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 warmings before purchase NDC 21130-381-34

Compare To Imodium® A-D active ingredient*

LOPERAMIDE HYDROCHLORIDE ORAL SOLUTION 1 mg per 7.5 mL

ANTI-DIARRHEAL ORAL SOLUTION

MINT FLAVOR

Controls the symptoms of diarrhea
Anti-Diarrheal Oral Solution

SEE NEW WARNING AND DIRECTIONS

8 FL OZ (240 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: BETTER LIVING BRANDS LLC P.O. BOX 99 PLEASANTON, CA 94566-0009

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Scan here for more information



Drug Facts (continued)

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)

Drug Facts (continued)

Directions

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
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adults and children
12 years and over
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

Drug Facts (continued) Drug Facts (continued) 15 mL after the first loose stool; children 6-8 years Inactive ingredients anhydrous citric acid, 7.5 mL after each subsequent (48-59 lbs) carboxymethylcellulose sodium, D&C yellow no. 10, loose stool: but no more than FD&C blue no. 1, glycerin, microcrystalline cellulose, 30 mL in 24 hours natural and artificial mint flavor, propylene glycol, purified water, simethicone, sodium benzoate, children 2-5 years ask a doctor sucralose, titanium dioxide, xanthan gum (34 to 47 lbs) children under do not use Questions or comments? 2 years 1-800-719-9260 (up to 33 lbs) Other information each 30 mL contains: sodium 15 mg store between 20-25°C (68-77°F)

ANTI-DIARRHEAL

loperamide hydrochloride solution

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Prod	UCT	ıntorr	nation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-381

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE UNII:6X90C3H4II) LOPERAMIDE HYDROCHLORIDE 1 mg in 7.5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
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)	
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			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:21130-381- 34	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2024	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA091292	10/15/2024	

Labeler - Safeway (009137209)

Revised: 10/2024 Safeway