SIGNATURE CARE ANTI DIARRHEAL- loperamide hcl solution Safeway

Better Living Brands LLC Anti-Diarrheal Oral Solution 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

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
` '	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours
,	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 Imodium® A-D active ingredient

Quality Guaranteed

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)

Drug Facts

Active ingredient Purpose (in each 7.5 mL)

Loperamide HCl 1 mg......Anti-diamheal

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 HCI

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

Do not use if you have bloody or black stool

Peel open to read complete directions and warnings before purchase



Compare to Imodium® A-D active ingredient*

Quality Guaranteed NDC 21130-440-34

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

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

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: 64534 LJ F3

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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
- 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

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
- 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; 12 years and over 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours

15 mL after the first loose stool; children 9-11 years 7.5 mL after each subsequent (60-95 lbs) loose stool; but no more than 45 mL in 24 hours

Drug Facts (continued)

children 6-8 years 15 mL after the first loose stool; (48-59 lbs) 7.5 mL after 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 do not use 2 years

Other information

(up to 33 lbs)

■ each 30 mL contains: sodium 15 mg ■ store between 20-25°C (68-77°F)

Drug Facts (continued)

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

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Imodium® A-D.

SIGNATURE CARE ANTI DIARRHEAL

loperamide hcl solution

Product	Information
Product	IIIIVI IIId UVII

Product Type HUMAN OTC DRUG Item Code (Source) NDC:21130-440

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE UNII:6 X9 OC3H4II) LOPERAMIDE HYDROCHLORIDE in 7.5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GLYCERIN (UNII: PDC6A3C0OX)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
XANTHAN GUM (UNII: TTV12P4NEE)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics			
Color	GREEN (opaque, viscous)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

ı	Packaging				
ı	# I	tem Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC	C:21130-440-34	1 in 1 CARTON	07/12/2018	
	1		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Infor	keting Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

ANDA ANDA091292 07/12/2018

Labeler - Safeway (009137209)

Revised: 5/2020 Safeway