DG HEALTH ANTI DIARRHEAL- loperamide hcl solution Dolgencorp Inc

Dolgencorp, LLC Anti-Diarrheal 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?

1-888-309-9030

Package/Label Principal Display Panel

SEE NEW WARNING AND DIRECTIONS

Compare to the active ingredient of Imodium® A-D

Loperamide Hydrochloride Oral Solution 1 mg per 7.5 mL

Anti-Diarrheal

Controls the Symptoms of Diarrhea

Anti-Diarrheal Oral Solution

Mint Flavor

4 FL OZ (118mL)

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

Peel open to read complete directions and warmings before purchase

DG™health

SEE NEW WARNING AND DIRECTIONS

Compare to the active ingredient of Imodium® A-D*

Loperamide Hydrochloride Oral Solution 1 mg per 7.5 mL

Anti-Diarrheal

Controls the Symptoms of Diarrhea Anti-Diarrheal Oral Solution

Mint Flavor

4 FLOZ (118mL)

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

DISTRIBUTED BY OLD EAST MAIN CO. 100 MISSION RIDGE GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed! (888) 309-9030

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



CODE

: 64526 VT 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





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? 1-888-309-9030

loperamide hcl solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-867

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 FORM (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: 92RU3N3Y10)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		

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

ı	Pa	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:55910-867- 26	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/27/2022	

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

ANDA ANDA091292 07/27/2022

Labeler - Dolgencorp Inc (068331990)

Revised: 7/2022 Dolgencorp Inc