GOOD NEIGHBOR PHARMACY LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution Amerisource Bergen

Amerisource Bergen Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL 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
(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
(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?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Imodium® A-D active ingredient See New Warning and Directions Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL anti-diarrheal Controls the Symptoms of Diarrhea

mint flavor

anti-diarrheal oral solution 4 fl oz (120 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 HCI Heart alert: Taking more than directed can cause serious heart problems or death

Peel open to read complete directions and warnings before purchase



Imodium® A-D active ingredient* NDC 46122-544-26

Compare to

See New Warning and Directions

Loperamide Hydrochloride

Oral Solution, 1 mg per 7.5 mL anti-diarrheal

Controls the Symptoms of Diarrhea

mint flavor anti-diarrheal oral solution

4 fl oz (120 mL)



Drug Facts (continued)	C
Do not use if you have bloody or black stool	C
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.	\subset
When using this product tiredness,	C
drowsiness or dizziness may occur. Be careful	
when driving or operating machinery.	C
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. 	C
If pregnant or breast-feeding, ask a	C
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)	C
Directions drink plenty of clear fluids to help	
prevent dehydration caused by diarrhea I find right dose on chart.	
If possible, use weight to dose; otherwise	-
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Drug Facts (conti	nued)			
 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 on commented 4 and 740 and			

Questions or comments? 1-800-719-9260

GOOD NEIGHBOR PHARMACY LOPERAMIDE HYDROCHLORIDE loperamide hcl solution **Product Information Product** Type HUMAN OTC DRUG Item Code (Source) NDC:46122-544 **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient** Name **Basis of Strength** Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE -LOPERAMIDE 1 mg UNII:6X9OC3H4II) HYDROCHLORIDE 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 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 Size Shape MINT Flavor **Imprint** Code Contains Packaging Marketing Start Date Marketing End Date Item Code Package Description # 1 NDC:46122-544-26 120 mL in 1 BOTTLE; Type 0: Not a Combination Product 08/13/2018

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA091292	08/13/2018			

Labeler - Amerisource Bergen (007914906)

Revised: 1/2020

Amerisource Bergen