

IMODIUM A-D- loperamide hydrochloride solution
Kenvue Brands LLC

IMODIUM

A-D

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 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 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 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 16 mg**
- store between 20-25°C (68-77°F)
- **do not use if outer neck band imprinted with "Imodium®" or inner neck band imprinted with "Sealed For Your Safety" is broken or missing**

Inactive ingredients

anhydrous citric acid, caramel color, D&C yellow no. 10, FD&C blue no. 1, flavor, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, simethicone emulsion, sodium benzoate, sucralose, titanium dioxide, xanthan gum

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-134-08

Imodium®
A-D

Loperamide HCl Oral Solution

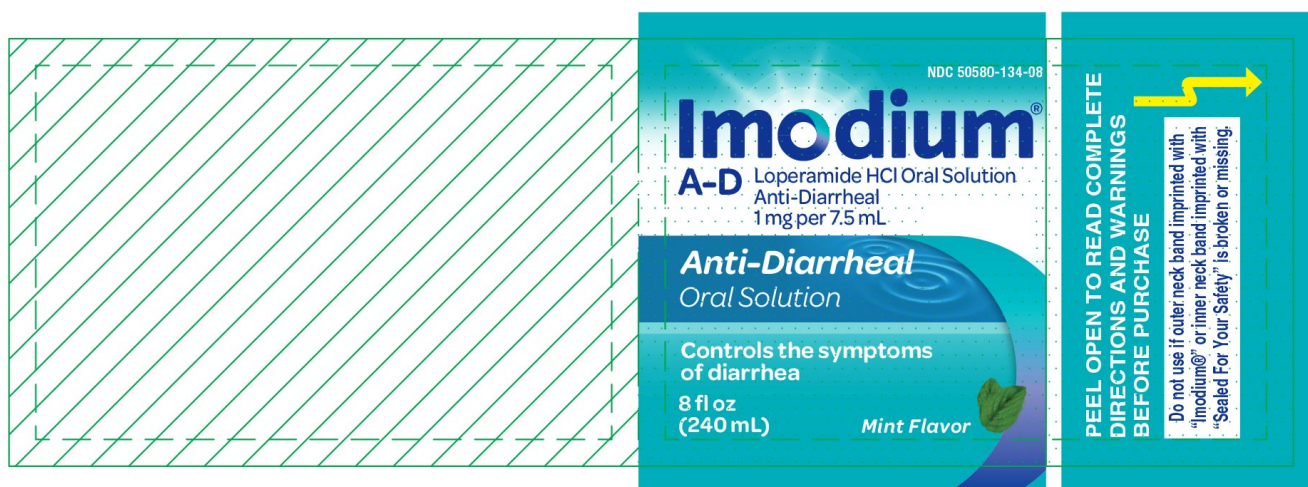
Anti-Diarrheal
1 mg per 7.5 mL

Anti-Diarrheal
Oral Solution

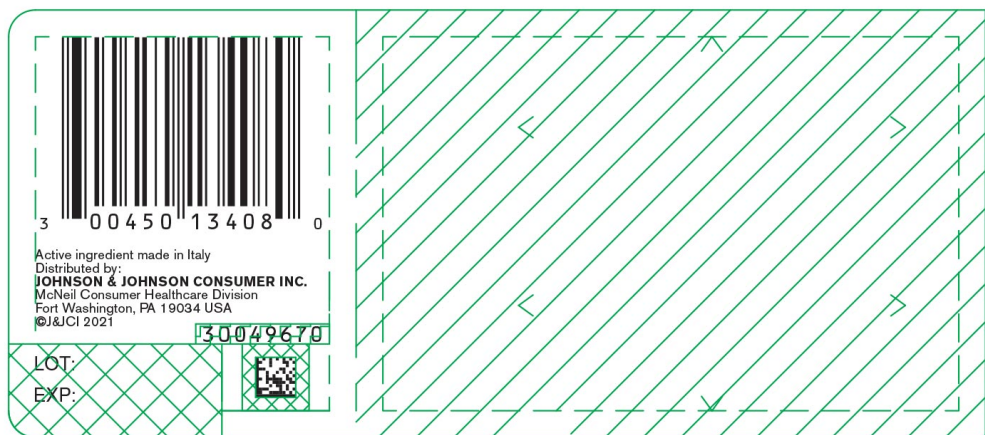
Controls the symptoms
of diarrhea

8 fl oz
(240 mL)

Mint Flavor



Drug Facts Active ingredient (in each 7.5 mL) Purpose 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 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.	Drug Facts (continued) 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.	Drug Facts (continued) ■ 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 first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours children 6-8 years (40-59 lbs) 15 mL after 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 16 mg	Drug Facts (continued) ■ store between 20-25°C (68-77°F) ■ do not use if outer neck band imprinted with "Imodium®" or inner neck band imprinted with "Sealed For Your Safety" is broken or missing Inactive ingredients anhydrous citric acid, caramel color, D&C yellow no. 10, FD&C blue no. 1, flavor, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, purified water, simethicone emulsion, sodium benzoate, sucralose, titanium dioxide, xanthan gum Questions or comments? call 1-877-895-3665 (toll-free) or 215-273-8755 (collect) Imodium® A-D Loperamide HCl Oral Solution Anti-Diarrheal 1 mg per 7.5 mL www.imodium.com
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IMODIUM A-D

loperamide hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-134
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
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CARMEL (UNII: T9D99G2B1R)	

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)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color	green (opaque)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-134-04	120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	07/01/2004	
2	NDC:50580-134-44	120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	07/01/2004	
3	NDC:50580-134-08	240 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	07/01/2004	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019487	07/01/2004	

Labeler - Kenvue Brands LLC (118772437)