

**IMODIUM A-D- loperamide hydrochloride solution**  
**Johnson & Johnson Consumer Inc.**

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**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

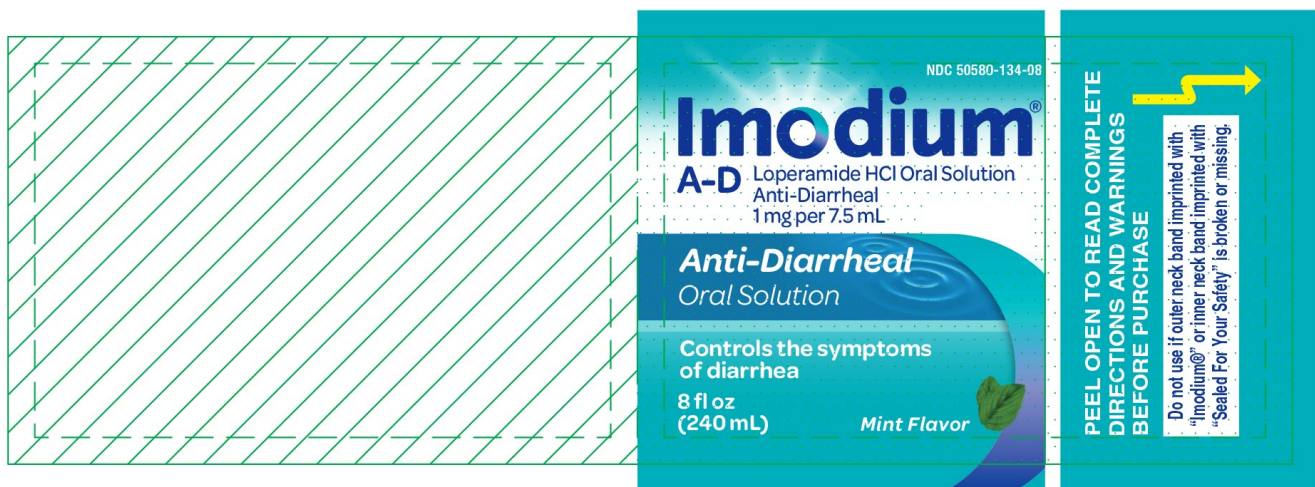
Anti-Diarrheal  
1 mg per 7.5 mL

**Anti-Diarrheal**  
Oral Solution

Controls the symptoms  
of diarrhea

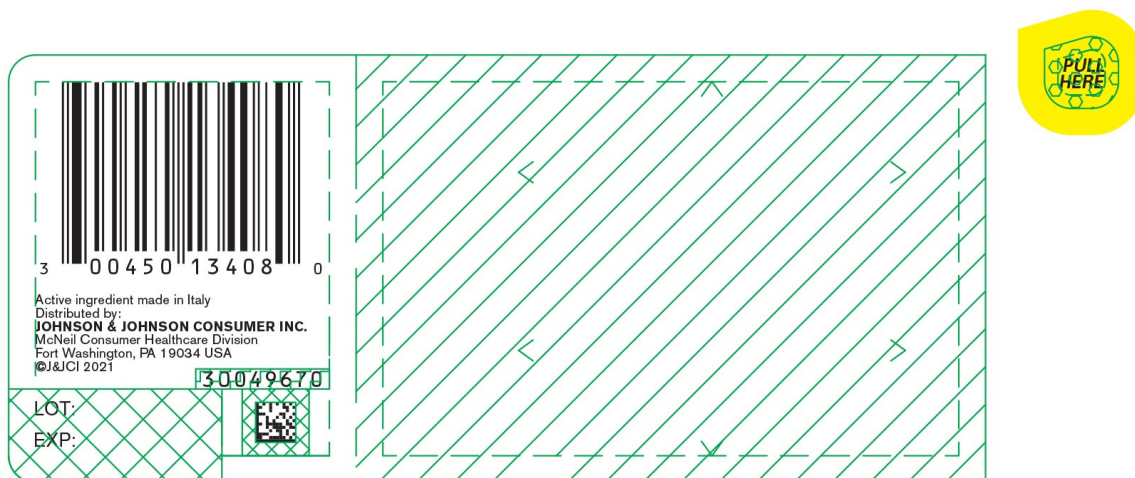
8 fl oz  
(240 mL)

Mint Flavor



<b>Drug Facts</b> <b>Active ingredient (in each 7.5 mL)</b> Purpose Loperamide HCl 1 mg.....Anti-diarrheal	<b>Drug Facts (continued)</b> When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery. <b>Stop use and ask a doctor if</b> ■ symptoms get worse ■ diarrhea lasts for more than 2 days ■ you get abdominal swelling or bulging. These may be signs of a serious condition.
<b>Use</b> controls symptoms of diarrhea, including Travelers' Diarrhea	<b>Directions</b> ■ 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.
<b>Warnings</b> <b>Allergy alert:</b> Do not use if you have ever had a rash or other allergic reaction to loperamide HCl <b>Heart alert:</b> Taking more than directed can cause serious heart problems or death <b>Do not use</b> if you have bloody or black stool <b>Ask a doctor before use if you have</b> ■ fever ■ mucus in the stool ■ a history of liver disease ■ a history of abnormal heart rhythm <b>Ask a doctor or pharmacist before use if you are taking a prescription drug.</b> Loperamide may interact with certain prescription drugs.	<b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

<b>Drug Facts (continued)</b> ■ 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	<b>Drug Facts (continued)</b> ■ 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 <b>Inactive ingredients</b> 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 <b>Questions or comments?</b> call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)
<b>Other information</b> ■ each 30 mL contains: sodium 16 mg	<b>Imodium®</b> <b>A-D</b> Loperamide HCl Oral Solution Anti-Diarrheal 1 mg per 7.5 mL <a href="http://www.imodium.com">www.imodium.com</a>



## IMODIUM A-D

loperamide hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-134
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77T135393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	

<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)

### Product Characteristics

<b>Color</b>	green (opaque)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### 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** - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.