

**LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution**  
**Rite Aid Corporation**

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**Rite Aid Corporation Loperamide Hydrochloride 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**

**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 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?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

Compare to the active ingredient in 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

8 FL OZ (240 mL)

<p><b>Drug Facts</b></p> <table border="1"> <tr> <th>Active ingredient (in each 7.5 mL)</th> <th>Purpose</th> </tr> <tr> <td>Loperamide HCl 1 mg.....</td> <td>Anti-diarrheal</td> </tr> </table> <p><b>Use</b> controls symptoms of diarrhea, including Travelers' Diarrhea</p> <p><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</p> <p>Do not use if you have bloody or black stool</p>	Active ingredient (in each 7.5 mL)	Purpose	Loperamide HCl 1 mg.....	Anti-diarrheal	<p>Compare to the active ingredient in Imodium® A-D*</p> <p><b>LOPERAMIDE HYDROCHLORIDE</b>  Oral Solution, 1 mg per 7.5 mL</p> <p><b>ANTI-DIARRHEAL</b></p> <p>Controls the symptoms of diarrhea  Anti-Diarrheal Oral Solution</p> <p><b>MINT FLAVOR</b></p> <p>8 FL OZ (240 mL)</p>	<p>0 11822 72924 6</p> <p><b>DO NOT USE IF PRINTED PLASTIC NECKBAND IS BROKEN OR MISSING.</b></p> <p><b>DISTRIBUTED BY:</b> RITE AID, 200 NEWBERRY COMMONS ETTERS, PA 17319  www.riteaid.com</p> <p><b>SATISFACTION GUARANTEE:</b>  If you're not satisfied, we'll happily refund your money.</p> <p>*This product is not manufactured or distributed by Johnson &amp; Johnson Consumer Inc., distributor of Imodium® A-D.</p> <p>EXP LOT : 64534 83 F5</p>
Active ingredient (in each 7.5 mL)	Purpose					
Loperamide HCl 1 mg.....	Anti-diarrheal					

Peel open to read complete directions and warnings before purchase

<p><b>Drug Facts (continued)</b></p> <p><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</p> <p><b>Ask a doctor or pharmacist before use if you are</b> taking a prescription drug. Loperamide may interact with certain prescription drugs.</p> <p><b>When using this product</b> tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.</p> <p><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.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><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)</p>	<p><b>Drug Facts (continued)</b></p> <p><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.  ■ mL = milliliter</p> <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours</td> </tr> <tr> <td>children 9-11 years (60-95 lbs)</td> <td>15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours</td> </tr> </table>	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	<p><b>ADHESIVE AREA NO COPY</b></p>
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VARNISH  
AREA**

**Drug Facts (continued)**

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**Questions or comments?**

1-800-719-9260

**LOPERAMIDE HYDROCHLORIDE**

loperamide hcl solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-5519
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<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>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	GREEN (opaque, viscous)	<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:11822-5519-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2018	08/30/2024
2	NDC:11822-5519-2	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2018	
3	NDC:11822-5519-3	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020	03/01/2020

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	06/18/2018	

**Labeler** - Rite Aid Corporation (014578892)

Revised: 6/2024

Rite Aid Corporation