

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride oral solution
Bionpharma Inc.

a+ health-Loperamide HCL Oral Solution, USP

Drug Facts

Active ingredient (in each 7.5 mL)

Loperamide HCl, USP 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 years to 11 years (60 lbs to 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 years to 8 years (48 lbs to 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 years to 5 years (34 lbs to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- each 30 mL contains: **sodium 7 mg**
- store at 20°C to 25°C (68°F to 77°F)
- **do not use if outer neck band is broken or missing.**

Inactive ingredients

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

Questions or comments?

call toll-free **1-888-235-2466**

Do not use if outer neck band is broken or missing

PEEL OPEN TO READ COMPLETE DIRECTIONS AND WARNINGS BEFORE PURCHASE

*This product is not manufactured or distributed by the owners of Imodium[®] A-D.

Code: TN/Drugs/TN00002222/2006

L0001188 R1125 948006945

Distributed by:

BIONPHARMA INC.

Princeton, NJ 08540

MADE IN INDIA

PRINCIPAL DISPLAY PANEL-8 fl oz

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

a+ health™

Loperamide HCl Oral Solution, USP

1 mg per 7.5 mL

Anti-Diarrheal Oral Solution

Controls the symptoms of diarrhea

Mint Flavor

8 fl oz (240 mL)

<p>*compare to the active ingredient in Imodium® A-D</p> <p>a+health™</p> <p>loperamide HCl oral solution, USP 1 mg per 7.5 mL anti-diarrheal oral solution</p> <p>controls the symptoms of diarrhea</p> <p>mint flavor</p> <p>8 fl oz (240 mL)</p> 	<p>Do not use if outer neck band is broken or missing</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each 7.5 mL)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Loperamide HCl, USP 1 mg.....</td> <td>Anti-diarrheal</td> </tr> </tbody> </table> <p>Use controls symptoms of diarrhea, including Travelers' Diarrhea</p> <p>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</p> <p>Do not use if you have bloody or black stool</p>	Active ingredient (in each 7.5 mL)	Purpose	Loperamide HCl, USP 1 mg.....	Anti-diarrheal	<p><small>*This product is not manufactured or distributed by the owners of Imodium® A-D.</small></p>	<p>L0001188 R1125 948006945 Code: TN/Drugs/TN0000222/2006</p>	<p>Distributed by: BIONPHARMA INC. Princeton, NJ 08540 MADE IN INDIA</p>  <p>69452 40593 2</p>	<p>UVZ 15 mm x 40 mm (Lot and Exp online Printing)</p> <p>PEEL OPEN TO READ COMPLETE DIRECTIONS AND WARNINGS BEFORE PURCHASE</p>
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<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ fever ■ mucus in the stool ■ a history of liver disease ■ a history of abnormal heart rhythm <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.</p> <p>When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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)</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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>No Text area</p>
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T0036R1125

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PRINCIPAL DISPLAY PANEL-4 fl oz

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

a+ health™

for ages 6 years & up

Loperamide HCl Oral Solution, USP

1 mg per 7.5 mL

Anti-Diarrheal Oral Solution

Controls the symptoms of diarrhea

Mint Flavor

4 fl oz (120 mL)

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Distributed by: **BIONPHARMA INC.**
Princeton, NJ 08540

MADE IN INDIA

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UVZ
15 mm x 33 mm
(Lot and Exp online Printing)

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LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride oral solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-405
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CARAMEL (UNII: T9D99G2B1R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT (flavadow coolmint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-405-55	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/02/2026	
2	NDC:69452-405-93	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA220100	03/02/2026	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
OrBion Pharmaceuticals Private Limited		854403569	manufacture(69452-405)

Revised: 2/2026

Bionpharma Inc.