

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE- loperamide hydrochloride and simethicone tablet**  
**Bionpharma Inc.**

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**Bion Loperamide Simethicone Tablets**

***Drug Facts***

**Active ingredients (in each caplet)**

Loperamide HCl, USP 2 mg  
Simethicone, USP 125 mg

**Purposes**

Anti-diarrheal

Anti-gas

**Uses**

relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

**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
- if you have difficulty swallowing

**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.
- you have difficulty swallowing the caplet

**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**
- take only on an empty stomach (1 hour before or 2 hours after a meal)
- take with a full (8 oz.) glass of water
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9 years to 11 years (60 lbs to 95 lbs)	1 caplet after the first loose stool; $\frac{1}{2}$ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6 years to 8 years (48 lbs to 59 lbs)	1 caplet after the first loose stool; $\frac{1}{2}$ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children 2 years to 5 years (34 lbsto 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

## **Other information**

- each caplet contains: **calcium 155 mg, sodium 3 mg**
- store between 20° to 25°C (68° to 77°F). Protect from light.

## **Inactive ingredients**

acesulfame potassium, anhydrous dicalcium phosphate, colloidal silicon dioxide, croscarmellose sodium, microcrystalline cellulose, stearic acid, vanilla flavor

## **Questions or comments?**

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

\*\*\*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Imodium<sup>®</sup> Multi-Symptom Relief

**THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**Manufactured for:**

**BIONPHARMA**

**600 Alexander Road,  
Princeton, NJ 08540**

**MADE IN INDIA**

Rev # 09/19

L0000000

## **PRINCIPAL DISPLAY PANEL**

\*\*\* **Compare** to the active ingredients in **Imodium<sup>®</sup> Multi-Symptom Relief**

**NDC 69452-210-04**

**Loperamide HCl  
and Simethicone Tablets,  
2 mg/125 mg**

**Antidiarrheal/Anti-gas**

**Multi-Symptom Relief**

**Caplet**

**Relieves symptoms of diarrhea *plus***

- **Cramps & Pressure**
- **Bloating**
- **Gas**

Actual Size

6 Caplets\*

\*Capsule-shaped Tablets

# Loperamide HCl and Simethicone Tablets, 2 mg/125 mg

Antidiarrheal/Anti-gas

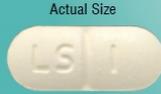
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NDC 69452-210-04

# Loperamide HCl and Simethicone Tablets, 2 mg/125 mg

## Antidiarrheal/Anti-gas

Multi-Symptom Relief  
Caplet



Actual Size

Relieves symptoms of diarrhea *plus*

- Cramps & Pressure
- Bloating
- Gas

6 Caplets\*

\*Capsule-shaped Tablets

Manufactured for:  
**BIONPHARMA**  
600 Alexander Road  
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Lot #  
Expiration Date  
Rev # 09/19  
L0000000



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THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BUSTERS ARE INTACT.  
KEEP OUT OF REACH OF CHILDREN. SEE IMPORTANT WARNINGS AND PRODUCT INFORMATION.

# Loperamide HCl and Simethicone Tablets, 2 mg/125 mg

Antidiarrheal/Anti-gas

**Drug Facts (continued)**  
**Inactive ingredients:** acesulfame potassium, anhydrous dicalcium phosphate, colloidal silicon dioxide, croscarmellose sodium, microcrystalline cellulose, stearic acid, vanilla flavor  
**Questions or comments?** call toll-free 1-888-235-2466

**Directions**  
 Simethicone, USP 125 mg  
 Loperamide HCl, USP 2 mg  
 Ant-gas

**Uses** relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

**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 ■ if you have difficulty swallowing

**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.

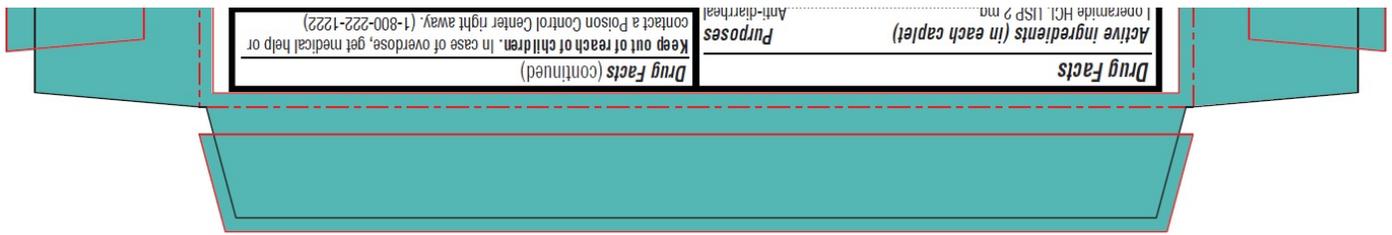
**When using this product** tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

**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.

**Other information**  
 ■ each caplet contains: calcium 155 mg, sodium 3 mg  
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adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9 years to 11 years (60 lbs to 95 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6 years to 8 years (48 lbs to 59 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 2 caplets 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



# LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69452-210
<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	2 mg
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>VANILLA</b> (UNII: Q74T35078H)	

## Product Characteristics

<b>Color</b>	white (off-white)	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	LS1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-210-04	1 in 1 CARTON	12/19/2021	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69452-210-12	4 in 1 CARTON	12/19/2021	

2	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213484	12/01/2021	

**Labeler** - Bionpharma Inc. (079637826)

**Registrant** - Bionpharma Inc. (079637826)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
OrBion Pharmaceuticals Private Limited		854403569	manufacture(69452-210)

Revised: 12/2025

Bionpharma Inc.