

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

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® 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® 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

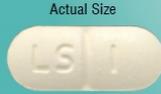
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NDC 69452-210-04

Loperamide HCl and Simethicone Tablets, 2 mg/125 mg

Antidiarrheal/Anti-gas

Multi-Symptom Relief
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Actual Size

Relieves symptoms of diarrhea *plus*

- Cramps & Pressure
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6 Caplets*

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Manufactured for:
BIONPHARMA
600 Alexander Road
Princeton, NJ 08540
MADE IN INDIA

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. READ THE COMPLETE DIRECTIONS, WARNINGS AND PRODUCT INFORMATION.

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69452 21004
8

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 mgAnti-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

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- if you have difficulty swallowing

Ask a doctor before use if you have

- fever
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Other information

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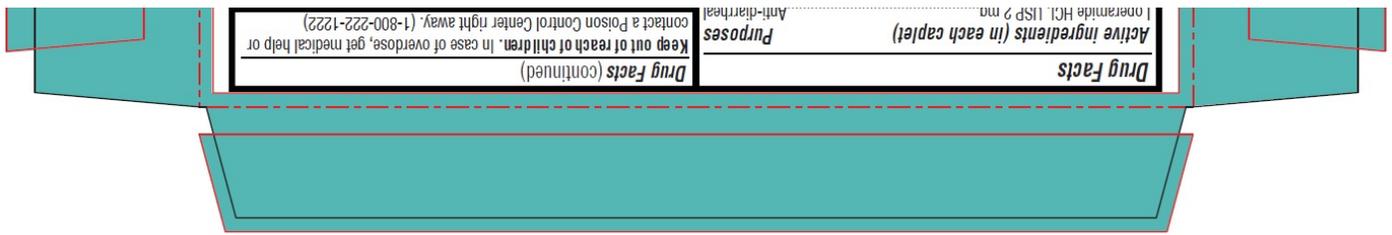
adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9 years to 11 years (60 lbs to 95 lbs)	1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more 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

find right dose on chart below. If possible, use weight to dose; otherwise, use age.

take with a full (8 oz.) glass of water

take only on an empty stomach (1 hour before or 2 hours after a meal)

diarrhea



LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-210
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

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

Product Characteristics

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

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		
Marketing Information			
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)

Establishment

Name	Address	ID/FEI	Business Operations
Recipharm Pharmservices Pvt. Ltd.		871401927	manufacture(69452-210)

Revised: 10/2021

Bionpharma Inc.