

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; 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

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**

†This product is not manufactured or distributed by the owners of Imodium® Multi-Symptom Relief

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Manufactured for:

BIONPHARMA

Princeton, NJ 08540

MADE IN INDIA

L0001183

R1025

Code: TN/Drugs/TN00002222/2006

949129361

PRINCIPAL DISPLAY PANEL

†Compare to the active ingredients in **Imodium® Multi-Symptom Relief**
anti-diarrheal/anti-gas

Loperamide HCl and simethicone tablets, 2 mg/125 mg
multi-symptom relief caplet

Relieves symptoms of diarrhea *plus*

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

24 Caplets*

*Capsule-shaped Tablets



anti-diarrheal/anti-gas

loperamide HCl and simethicone tablets, 2 mg/125 mg

multi-symptom relief caplet

[†]compare to the active ingredient in Imodium® Multi-Symptom Relief



anti-diarrheal/anti-gas

loperamide HCl and simethicone tablets, 2 mg/125 mg

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24 caplets*

*capsule-shaped tablets

relieves symptoms of diarrhea *plus*

- cramps & pressure
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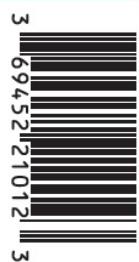
anti-diarrheal/anti-gas

loperamide HCl and simethicone tablets, 2 mg/125 mg

Manufactured for:
BIONPHARMA INC.
Princeton, NJ 08540
MADE IN INDIA

L001183 R1026
Code: TM/Drugs/N00002222/2006
949129561

UVZ
45 mm x 36 mm
(Lot and Exp online Printing)



WARNING: KEEP OUT OF REACH OF CHILDREN.
KEEP OUT OF REACH OF CHILDREN. IN CASE OF OVERDOSE, GET MEDICAL HELP IMMEDIATELY. CALL 911 OR POISON CONTROL CENTER RIGHT AWAY. (1-800-222-1222)

Drug Facts (continued)	Uses	Warnings	Directions	Directions	Other Information
After meals, 2 caplets (1 each caplet) Prolonged use of loperamide HCl USP 2 mg - Anti-diarrheal	Relieves symptoms of diarrhea plus bloating, cramps, and constipation, referred to as gas.	Do not use if you have an empty stomach (1 hour before or 2 hours after meals). Do not use if you have had a rash or other allergic reaction to loperamide HCl.	Take 2 caplets after the first loose stool. If diarrhea continues, take 2 caplets after each subsequent loose stool, but no more than 2 caplets in 24 hours.	Take 2 caplets after the first loose stool. If diarrhea continues, take 2 caplets after each subsequent loose stool, but no more than 2 caplets in 24 hours.	Ask a doctor before use if you have a history of stomach or bowel problems.
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LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-531
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: 230V73Q5G9)	
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	LII
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-531-12	4 in 1 CARTON	01/07/2026	
1		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	01/07/2026	

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

Name	Address	ID/FEI	Business Operations
OrBion Pharmaceuticals Private Limited		854403569	manufacture(69452-531)

Revised: 1/2026

Bionpharma Inc.