

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE- loperamide hydrochloride
and simethicone tablet
IMO-GEN LABS LLC**

IBS-10 Loperamide Simethicone

ACTIVE INGREDIENT(S)

(in each tablet)

Loperamide Hydrochloride USP 2 mg

Simethicone USP 125 mg

PURPOSES

Anti-diarrheal

Anti-gas

USE(S)

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 hydrochloride

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 tablet

If pregnant or breast-feeding, ask a health professional before use.

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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 tablets after the first loose stool; 1 tablet after each subsequent loose stool; but no more than 4 tablets in 24 hours
children 9-11 years (60-95 lbs)	1 tablet after the first loose stool; 1/2 tablet after each subsequent loose stool; but no more than 3 tablets in 24 hours
children 6-8 years (48-59 lbs)	1 tablet after the first loose stool; 1/2 tablet after each subsequent loose stool; but no more than 2 tablets 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 tablet contains: **calcium 640 mg, very low sodium and potassium 5.838 mg**
- store between 20 to 25°C (68 to 77°F). Protect from light.
- **do not use if carton is open or if blister unit is open or torn**

INACTIVE INGREDIENTS

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, microcrystalline cellulose, stearic acid and vanilla flavor

Loperamide Hydrochloride and Simethicone Tablets 2 mg/125 mg

8 60010 27812 3



Compare to the active ingredient in
Imodium® Multi-Symptom Relief

IBS LABS

MULTI-SYMPTOM RELIEF

ANTI-DIARRHEAL & ANTI-GAS

LOPERAMIDE HCl 2 MG / SIMETHICONE 125 MG

VALUE SIZE
100
CAPLETS

RELIEVES SYMPTOMS
OF DIARRHEA *PLUS*

- CRAMPS & PRESSURE
- BLOATING • GAS

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each tablet) Purpose
Loperamide Hydrochloride USP 2 mg.....Anti-diarrheal
Simethicone USP 125 mg.....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 hydrochloride

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 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 ■ if you get abdominal swelling or bulging. These may be signs of a serious condition ■ you have difficulty swallowing the tablet

LIFT HERE

PEEL FOR DIRECTIONS G7811-200-111-0

Drug Facts (continued)

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; other wise, use age.

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Questions? call toll-free 1-866-933-6337

†This product is not manufactured or distributed by the owner of the registered trademark Imodium® Multi-Symptom Relief.

Distributed by:
IBS LABS
Wilmington, DE 19801



Available at
wellspringrx.com

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84441-713
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE	Size	17mm
Flavor	VANILLA	Imprint Code	H;L21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84441-713-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/23/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211438	10/23/2025	

Labeler - IMO-GEN LABS LLC (119282683)

Revised: 10/2025

IMO-GEN LABS LLC