

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride
and simethicone tablet
NORTHEAST PHARMA**

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

Other information

- each caplet contains: **calcium 165 mg, sodium 4 mg**
- store between 20° to 25°C (68° to 77°F). Protect from light.
- **do not use if carton is opened or if individual blister units are torn or opened**

Inactive ingredients

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate anhydrous, flavor, microcrystalline cellulose, stearic acid.

Questions or comments?

call 1-855-274-4122

(Monday - Friday 8:30 AM to 5:00 PM EST)

Dist. By: Northeast Pharma
South Burlington, VT 05403
1-800-383-0648

Made in India

Code: AP/DRUGS/04/2016

REV 1021

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg/125mg (24 Caplets) Blister Carton Label

Heartland™

Pharna Co.

NDC 80136-384-24

**LOPERAMIDE HCl and
SIMETHICONE TABLETS
2 mg/125 mg**

LOPERAMIDE HCl 2 mg - ANTIDIARRHEAL / SIMETHICONE 125 mg - ANTI-GAS

Multi-Sympton Relief Caplet

Relieves symptoms of diarrhea *plus*

- Cramps & Pressure
- Bloating
- Gas

**Compare to the active ingredients of
*IMODIUM® MULTI-SYMPTON RELIEF*****

T 79

Actual Size

24 Caplets*

***capsule-shaped tablets**

No Coating Area

COATING FREE AREA

COATING FREE AREA

Drug Facts (continued)

Warnings

- Do not use if you are allergic to any of the ingredients listed in the inactive ingredients section.
- Do not use if you are allergic to any of the ingredients listed in the active ingredients section.
- Do not use if you are allergic to any of the ingredients listed in the inactive ingredients section.
- Do not use if you are allergic to any of the ingredients listed in the active ingredients section.

Directions

• Take 1 caplet 2 to 3 times a day after meals and at bedtime. Do not take more than 6 caplets in 24 hours.

Other information

• Each caplet contains 2 mg of loperamide HCl and 125 mg of simethicone.

Drug Facts (continued)

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NDC 80136-384-24

LOPERAMIDE HCl and SIMETHICONE TABLETS

2 mg/125 mg

LOPERAMIDE HCl 2 mg - ANTI-DIARRHEAL / SIMETHICONE 125 mg - ANTI-GAS

Multi-Symptom Relief Caplet
Relieves symptoms of Diarrhea **plus**
• Cramps & Pressure • Bloating • Gas



Compare to the active ingredients of **IMODIUM® MULTI-SYMPTOM RELIEF****

24 Caplets*

*capsule-shaped tablets

PF045350 LM-4690

NVZ Batch Coding Area

Unvarnish Zone (dotted line for perforation)

Lot: Exp:



Heartland Pharma Co.
Loperamide HCl and Simethicone Tablets
2 mg/125 mg
LOPERAMIDE HCl 2 mg - ANTI-DIARRHEAL
SIMETHICONE 125 mg - ANTI-GAS



Instructions for Opening Blister Pack

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80136-384
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE (off-white)	Score	2 pieces
Shape	CAPSULE	Size	17mm
Flavor	VANILLA	Imprint Code	T;79
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-384-24	4 in 1 CARTON	10/27/2021	
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	ANDA211059	10/27/2021	

Labeler - NORTHEAST PHARMA (081232935)**Registrant** - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(80136-384) , MANUFACTURE(80136-384)

Revised: 1/2025

NORTHEAST PHARMA