

**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-Symptom 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** ←

REV 102 1  
 CMC: APR 18 5042018  
 Made in India  
 1-800-483-0848  
 South Burlington, VT 05403  
 Dist. By: Northwest Pharma  
 Consumer Health Division  
 This product is not manufactured or distributed by Johnson & Johnson Consumer Inc. • McNeil Consumer Health Division, owner of the registered trademark Imodium® Multi-Symptom Relief.  
 Questions or comments? Call 1-855-274-4122 (Monday - Friday 8:00 AM to 5:00 PM EST)

**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.

**Other Information**

• Each caplet contains 2 mg loperamide hydrochloride and 125 mg simethicone.

**Drug Facts (continued)**

**Directions**

- Adults: Take 2 caplets 4 times a day after meals and at bedtime.
- Children 12 years of age and older: Take 1 caplet 4 times a day after meals and at bedtime.
- Children 6 to 11 years of age: Take 1 caplet 4 times a day after meals and at bedtime.
- Children 2 to 5 years of age: Take 1/2 caplet 4 times a day after meals and at bedtime.
- Children under 2 years of age: Do not use.

**Drug Facts (continued)**

**Other Information**

• Each caplet contains 2 mg loperamide hydrochloride and 125 mg simethicone.

**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.

**Other Information**

• Each caplet contains 2 mg loperamide hydrochloride and 125 mg simethicone.

**Drug Facts (continued)**

**Directions**

- Adults: Take 2 caplets 4 times a day after meals and at bedtime.
- Children 12 years of age and older: Take 1 caplet 4 times a day after meals and at bedtime.
- Children 6 to 11 years of age: Take 1 caplet 4 times a day after meals and at bedtime.
- Children 2 to 5 years of age: Take 1/2 caplet 4 times a day after meals and at bedtime.
- Children under 2 years of age: Do not use.

**Drug Facts (continued)**

**Other Information**

• Each caplet contains 2 mg loperamide hydrochloride and 125 mg simethicone.

NDC 80136-384-24

**Heartland**  
Pharma Co.

## 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

**COATING FREE AREA** ←

LOT: 1500021285244

8 1500021285244 1

2. Peel the back of the blister pack to remove the caplet.

1. Do not tear the blister pack.

**Instructions for Opening Blister Pack**



**COATING FREE AREA** →

PF045350    LM-4690

**NVZ**  
Batch Coding Area

Unvarnish Zone (dotted line for perforation)

Lot:      Exp:      :

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE**  
loperamide hydrochloride and simethicone tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80136-384
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MICROCRYSTALLINE CELLULOSE 101</b> (UNII: 7T9FYH5QMK)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

**Product Characteristics**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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: 12/2023

NORTHEAST PHARMA