

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet**  
**Aurohealth LLC**

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***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)

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

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

Healthy Living™

## **LOPERAMIDE HCl AND SIMETHICONE tablets 2 mg/125 mg**

### ***Multi-Sympton Relief Caplet***

**Loperamide HCl 2 mg - Antidiarrheal  
Simethicone 125 mg - Anti-gas**

**\*\* Compare  
to the active  
ingredients of  
Imodium®**

**Multi-Sympton  
Relief**

**Relieves symptoms of diarrhea *plus***

- Cramps & Pressure
- Bloating
- Gas

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**24 Caplets\***

**\*capsule-shaped tablets**



# LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-868
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CROSCARMELOSE 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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-868-76	4 in 1 CARTON	02/24/2021	
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	02/24/2021	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-868) , MANUFACTURE(58602-868)

Revised: 12/2023

Aurohealth LLC