

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

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

AUROHEALTH

NDC 58602-815-76

** Compare to the active
ingredients of Imodium® Multi-Sympton Relief

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**

24 Caplets*

***capsule-shaped tablets**

NDC:58602-815

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: 4ELV7Z 65AP)				
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:58602-815-74	1 in 1 CARTON	12/14/2020	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-815-75	2 in 1 CARTON	12/14/2020	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-815-80	3 in 1 CARTON	12/14/2020	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:58602-815-76	4 in 1 CARTON	12/14/2020	
4		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	12/14/2020	
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Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-815) , MANUFACTURE(58602-815)

Revised: 12/2023

Aurohealth LLC