

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride
and simethicone tablet
WALGREEN CO.**

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:

WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

Walgreens

**100% SATISFACTION
GUARANTEED**

walgreens.com

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MADE IN INDIA

Code: AP/DRUGS/04/2016

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

NDC 0363-9606-76

Walgreens

Compare to the active ingredients in
Imodium® Multi-Sympton Relief††

Anti - Diarrheal +

Anti - Gas

**LOPERAMIDE HCl & SIMETHICONE TABLETS, 2 mg/125 mg
ANTI-DIARRHEAL / ANTI-GAS**

Multi-Symptom Relief Caplet

- **Relieves symptoms of diarrhea plus:
Cramps & Pressure; Bloating; Gas**

24 CAPLETS*
 (*capsule-shaped tablets)

ACTUAL SIZE



ORG code is an internal Periscope code, that will be updated by Periscope prior to artwork release. It is okay to move this number, but do not remove.

W00000-0000-0 is a placeholder and must be updated with a unique Packaging Supplier Code issued by GMI for the Walgreens PQA Program. This code is required to be printed on all Walgreens packaging. Additionally, packaging must be produced by a GMI Certified packaging supplier. If the packaging supplier printing the packaging does not have a code they will need to contact GMI to obtain the code and begin the required Certification process by emailing: walgreensmonitoring@spsc.com

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9606
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:0363-9606-75	2 in 1 CARTON	08/03/2022	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-9606-76	4 in 1 CARTON	08/03/2022	
2		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	08/03/2022	

Labeler - WALGREEN CO. (008965063)**Registrant** - Aurohealth LLC (078728447)**Establishment**

Name	Address	ID/FEI	Business Operations
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Revised: 12/2023

WALGREEN CO.