

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet
Family Dollar Stores, 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: MIDWOOD BRANDS, LLC
500 VOLVO PKWY, CHESAPEAKE, VA 23320 USA
Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg/125mg (12 Caplets)
Blister Carton Label

FAMILY
Welness™

COMPARE TO THE ACTIVE
INGREDIENTS OF IMODIUM
MULTI-SYMPTON RELIEF**

Multi-Sympton Relief Caplet
ANTI-DIARRHEAL
Loperamide HCl and Simethicone Tablets
2 mg/125 mg

Loperamide HCl 2 mg - Antidiarrheal
Simethicone 125 mg - Anti-gas
Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

12 Caplets*
***CAPSULE-SHAPED TABLETS**

ACTUAL SIZE
NDC 55319-052-75



LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

COATING FREE AREA

FAMILY Wellness

Multi-Symptom Relief Caplet

ANTI-DIARRHEAL

Loperamide HCl and Simethicone Tablets 2 mg/125 mg

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

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

12 CAPLETS*

*CAPSULE-SHAPED TABLETS

ACTUAL SIZE



NDC 55319-052-75

COATING FREE AREA

Batch Coding Area

NVZ

P1052381

LM-5286

Lot: _____

Exp: _____

Instructions for Opening Blister Pack



1. Bend and tear
2. Peel off the foil
Blister at perforation
Gently push tablet out.

SKU 999348



0 3225192265 8

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Loperamide HCl USP 2 mg.....Anti-diarrheal
Simethicone USP 125 mg.....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

Drug Facts (continued)

■ 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 (travels, 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 bloating. These may be signs of a serious condition. ■ you have difficulty swallowing the caplet

■ 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. (Other uses, see 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

Drug Facts (continued)

■ 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 acetylsalicylic acid, croscarmellose sodium, dibasic calcium phosphate anhydrous, flavor, microcrystalline cellulose, stearic acid.

Other information

ask a doctor ■ children 2 to 5 years (34 to 47 lbs) ■ children under 2 years (up to 33 lbs)

do not use

children 6 to 8 years (48 to 59 lbs) ■ 1 caplet after the first loose stool; but no more than 2 caplets in 24 hours; caplet after each subsequent loose stool.

Drug Facts (continued)

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*This product is not a narcotic or controlled substance. Consumer Healthcare, owner of the registered trademark Imodium® Multi-Symptom Relief. Distributed by: MWOOD BRANDS, LLC 500 VOLVO PARKWAY, CHESAPEAKE, VA 23020 USA Code: APRRUGS/04/2016 NOT 100% SATISFIED Return within 30 days to any Family Dollar

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-052
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:55319-052-75	2 in 1 CARTON	08/11/2023	
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	08/11/2023	

Labeler - Family Dollar Stores, LLC (024472631)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(55319-052) , MANUFACTURE(55319-052)

Revised: 1/2025

Family Dollar Stores, LLC