

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet**  
**Family Dollar Stores, 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: 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\*\*

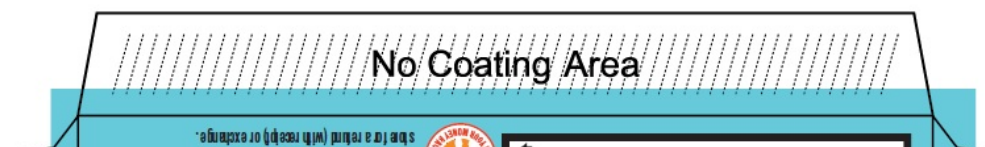
**Multi-Sympton Relief Caplet**  
**ANTI-DIARRHEAL**  
**Loperamide HCl and Simethicone Tablets**  
**2 mg/125 mg**

**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**



COATING  
FREE AREA

COATING  
FREE AREA

**Drug Facts (continued)**

**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)**

**Warnings**  
 ■ 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 ■ a history of other disease ■ a history of taking a prescription drug. Loperamide may interact with certain prescription drugs. **When using this product:** Irritation, 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 Poison Control Center right away. (1-800-222-1222)

NOT 100% Satisfying  
 Return in 30 days to any Family Dollar

**Drug Facts (continued)**

**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 open or if individual blister units are torn or opened. **Inactive ingredients**  
 acetylsalicylic acid, 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). **This product is not to be used or stored in a vehicle. Consumer Healthcare, owner of the registered trademark Imodium® Multi-Symptom Relief, is a registered trademark of Johnson and Johnson Consumer Inc. • Model 300 YOLVO ROW, CHESAPEAKE, VA 23020 USA**

DISPATCHED BY: MEDVAC BRANDS, LLC  
 Code: APPROB05/042016

**Drug Facts**  
**Active ingredients (in each caplet):** Loperamide HCl USP 2 mg; Antidiarrheal; Simethicone USP 125 mg; Anti-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 and cramps, commonly referred to as gas. **Uses:** relieves symptoms of diarrhea plus bloating, pressure.

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**Drug Facts (continued)**

**Drug Facts**  
 1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours; ask a doctor. Children 2 to 5 years (34 to 47 lbs); 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 open or if individual blister units are torn or opened. **Inactive ingredients:** acetylsalicylic acid, 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). **This product is not to be used or stored in a vehicle. Consumer Healthcare, owner of the registered trademark Imodium® Multi-Symptom Relief, is a registered trademark of Johnson and Johnson Consumer Inc. • Model 300 YOLVO ROW, CHESAPEAKE, VA 23020 USA**

DISPATCHED BY: MEDVAC BRANDS, LLC  
 Code: APPROB05/042016

**FAMILY Wellness**™

Multi-Symptom Relief Caplet

**ANTI-DIARRHEAL**  
 Loperamide HCl and Simethicone Tablets 2 mg/125 mg

**COMPARE TO THE ACTIVE INGREDIENTS OF IMODIUM® MULTI-SYMPTOM RELIEF**

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

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

**12 CAPLETS\***  
 \*CAPSULE-SHAPED TABLETS



NDC 55319-052-75

Batch Coding Area  
 Lot: \_\_\_\_\_  
 Exp.: \_\_\_\_\_

LM-5286 P1052381 NVZ



COATING  
FREE AREA

**ANTI-DIARRHEAL**  
 Loperamide HCl and Simethicone Tablets 2 mg/125 mg  
 12 CAPLETS\*  
 \*CAPSULE-SHAPED TABLETS

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-052
<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:55319-052-75	2 in 1 CARTON	08/11/2023	
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	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: 8/2023

Family Dollar Stores, LLC