

**ANTI-DIARRHEAL/ANTI-GAS - loperamide hydrochloride, simethicone tablet  
Harris Teeter, LLC**

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**Anti-diarrheal/ Anti-gas Multi-Symptom Relief**

**ACTIVE INGREDIENTS (in each caplet)**

Loperamide HCl 2 mg

Simethicone 125 mg

**PURPOSE**

Anti-diarrheal

Anti-gas

**USE(S)**

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 THE CHILD HAS**

- 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 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 9-11 years (60-95 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 6-8 years (48-59 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 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

### **OTHER INFORMATION**

- **each 10 mL contains:** calcium 180 mg, sodium 3 mg
- store between 20-25°C (68-77°F). Protect from light.
- do not use if blister unit is torn or broken

## **INACTIVE INGREDIENTS**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid

## **QUESTIONS OR COMMENTS**

Call 1-609-860-2600 (Monday-Friday 8 am- 4 pm)

## **PRINCIPAL DISPLAY PANEL**

Harris Teeter™

NDC 69256-265-31

## **MULTI-SYMPTOM RELIEF**

## **ANTI-DIARRHEAL/ANTI-GAS**

## **Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg**

Relieves Symptoms of Diarrhea Plus  
Cramps & Pressure  
Bloating, Gas

Compare to the active ingredients in Imodium®  
Multi-Symptom Relief Caplet\*

12 Caplets\*\*

\*\*Capsule-Shaped Tablets



Harris Teeter™

NDC 69256-265-73

**MULTI-SYMPTOM RELIEF  
ANTI-DIARRHEAL/ANTI-GAS**

**Loperamide Hydrochloride and Simethicone  
Tablets, 2 mg/125 mg**

Relieves Symptoms of Diarrhea Plus  
Cramps & Pressure  
Bloating, Gas

Compare to the active ingredients in Imodium®  
Multi-Symptom Relief Caplet\*

18 Caplets\*\*

\*\*Capsule-Shaped Tablets

**Drug Facts**

**Active ingredients (in each caplet)**  
 Loperamide HCl 2 mg  
 Simethicone 125 mg  
 Anti-diarrheal  
 Anti-gas

**Purposes**  
 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  
 Ask a doctor before use if you have difficulty swallowing  
 Ask a doctor before use if you have a history of liver disease, a history of abnormal heart rhythm, mucus in the stool, or fever  
 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  
 Symptoms get worse  
 You get abdominal swelling or bulging. These may be signs of a serious condition.  
 You have difficulty swallowing the caplet

**Other information**  
 Each caplet contains: calcium 180 mg, sodium 3 mg  
 Store between 20-25°C (68-77°F). Protect from light.  
 Do not use if blister unit is torn or broken

**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.

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children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

**Drug Facts (continued)**  
 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)



**MULTI-SYMP TOM RELIEF**

**ANTI-DIARRHEAL/ANTI-GAS**

Loperamide Hydrochloride and Simethicone  
 Tablets, 2 mg/125 mg



**MULTI-SYMP TOM RELIEF**

**ANTI-DIARRHEAL/ANTI-GAS**

Loperamide Hydrochloride and Simethicone  
 Tablets, 2 mg/125 mg

Relieves Symptoms of Diarrhea Plus  
 Cramps & Pressure  
 Bloating, Gas

Compare to the active ingredients in Imodium®  
 Multi-Symptom Relief Caplet \*



Actual size

**18**  
 CAPLETS\*\*

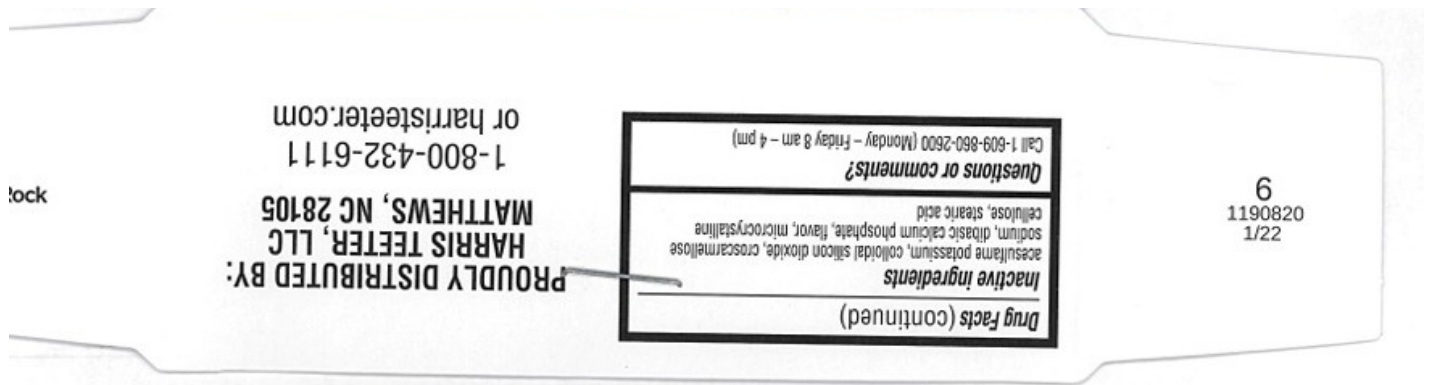
\*\*capsule-shaped tablets

\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of IMODIUM® Multi-Symptom Relief Caplet.

MFR 53041 REV 0721



LOT:



Harris Teeter™

NDC 69256-265-33

**MULTI-SYMPTOM RELIEF**

**ANTI-DIARRHEAL/ANTI-GAS**

**Loperamide Hydrochloride and Simethicone**

**Tablets, 2 mg/125 mg**

Relieves Symptoms of Diarrhea Plus

Cramps & Pressure

Bloating, Gas

Compare to the active ingredients in Imodium®

Multi-Symptom Relief Caplet\*

24 Caplets\*\*

\*\*Capsule-Shaped Tablets





ANTI-DIARRHEAL/ANTI-GAS			
loperamide hydrochloride, simethicone tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-265
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)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>	CARAMEL	<b>Imprint Code</b>	2;63
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69256-265-31	2 in 1 CARTON	02/05/2025	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69256-265-73	3 in 1 CARTON	02/05/2025	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69256-265-33	4 in 1 CARTON	02/05/2025	
3		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	ANDA214541	02/05/2025	

**Labeler** - Harris Teeter, LLC (048463103)

## Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(69256-265)

Revised: 2/2025

Harris Teeter, LLC