ANTI-DIARRHEAL/ANTI-GAS - loperamide hydrochloride, simethicone tablet Discount Drug Mart, Inc

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	2 caplets after the first loose stool; 1 caplet after each
12 years and over	subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years	1 caplet after the first loose stool; ½ caplet after each
(60-95 lbs)	subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years	1 caplet after the first loose stool; ½ caplet after each
(48-59 lbs)	subsequent loose stool; but no more than 2 caplets in 24 hours
children 2-5 years	ask a doctor
(34 to 47 lbs)	
children under 2	do not use
years (up to 33 lbs)	

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

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

*Compare to the Active Ingredients in IMODIUM® Multi-symptom Relief Caplet.

DISCOUNT drug mart

Anti-diarrheal/Anti-gas

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

Multi-symptom Relief Caplet

Relieves Symptoms of Diarrhea Plus

- Cramps & Pressure
- Bloating
- Gas

24 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*

24 Caplets**

**Capsule-Shaped Tablets



ANTI-DIARRHEAL/ANTI-GAS

loperamide hydrochloride, simethicone tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-263
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: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg	

Inactive Ingredients			
Ingredient Name	Strength		
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	WHITE	Score	2 pieces
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	2;63
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-263- 33	4 in 1 CARTON	02/26/2025	
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	ANDA214541	02/26/2025	

Labeler - Discount Drug Mart, Inc (047741335)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	MANUFACTURE(53943-263)	

Revised: 2/2025 Discount Drug Mart, Inc