

**LOPERAMIDE HYDROCHLORIDE, SIMETHICONE - loperamide hydrochloride,  
simethicone tablet  
Guardian Drug Company**

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**Loperamide and Simethicone Caplets**

**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 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 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 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**

NDC 53041-263-50

Multi-Symptom Relief Caplet

**Loperamide Hydrochloride and Simethicone**

**Tablets, 2 mg/125 mg**

Anti-diarrheal/Anti-gas

Relieves symptoms of diarrhea plus

Cramps & Pressure

Bloating

Gas

6 Caplets\*\*

\*\*capsule-shaped tablets

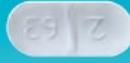
GLUE - NO COATING

\*\*capsule-shaped tablets

6 Caplets\*\*

- Gas
- Bloating
- Cramps & Pressure

Actual size



Anti-diarrheal/Anti-gas

Tablets, 2 mg/125 mg

# Loperamide Hydrochloride and Simethicone

Multi-Symptom Relief Caplet

NDC 53041-263-50

SEAL AREA  
INK FREE AREA

SEAL AREA  
INK FREE AREA

# Loperamide Hydrochloride and Simethicone

Multi-Symptom Relief Caplet

Tablets, 2 mg/125 mg

### Drug Facts

#### Active ingredients (in each caplet)

Loperamide HCl 2 mg  
Simethicone 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
- a history of liver disease
- mucus in the stool
- 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

### 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)

#### 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
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#### 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

EXP:

LOT:

### Drug Facts (continued)

#### 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)

Manufactured by: Guardian Drug Company  
2 Charles Court, Dayton, NJ 08810 USA

MFR 53041 REV 0420



**LOPERAMIDE HYDROCHLORIDE, SIMETHICONE**

loperamide hydrochloride, simethicone tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53041-263
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77T135393C) (LOPERAMIDE - UNII:6X90C3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (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 (caramel vanilla)	<b>Imprint Code</b>	2;63
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53041-263-50	1 in 1 CARTON	06/01/2021	
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	06/01/2021	

**Labeler** - Guardian Drug Company (119210276)

### Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(53041-263)

