

**CAREONE DIARRHEA AND GAS CONTROL- loperamide hydrochloride, simethicone tablet**  
**American Sales Company**

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**American Sales Company Diarrhea & Gas Control 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
- 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 9-11 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 165 mg, sodium 3 mg
- store between 20°-25° C (68°-77° F). Protect from light.
- **do not use if printed foil under cap is broken or torn**

**Inactive ingredients**

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, maltodextrin, microcrystalline cellulose, natural and artificial flavor, propylene glycol, stearic acid

**Questions or comments?**

**1-800-719-9260**

**Package/Label Principal Display Panel**

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

DIARRHEA & GAS CONTROL

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

Anti-Diarrheal/Anti-Gas

MULTI-SYMPTOM RELIEF CAPLET

RELIEVES SYMPTOMS OF DIARRHEA PLUS

CRAMPS & PRESSURE – BLOATING – GAS

GLUTEN FREE

Actual Size

OUR PHARMACISTS RECOMMEND

12 CAPLETS\*

\*CAPSULE-SHAPED TABLETS

CAREone®

# DIARRHEA & GAS CONTROL

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg  
Anti-Diarrheal/Anti-Gas

NDC 41520-772-53

CAREone®

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

# DIARRHEA & GAS CONTROL

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg  
Anti-Diarrheal/Anti-Gas

MULTI-SYMPTOM RELIEF CAPLET

RELIEVES SYMPTOMS OF DIARRHEA PLUS

• CRAMPS & PRESSURE • BLOATING • GAS

GLUTEN FREE



Actual Size



**12 CAPLETS\***

\*CAPSULE-SHAPED TABLETS

OR153 OF C2

### Drug Facts

**Active ingredients (in each caplet)** Purposes  
Loperamide HCl 2 mg ..... Anti-diarrhea  
Simethicone 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
- 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 an 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 a bad abdominal swelling or bloating. 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
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children under 2 years (up to 33 lbs)	do not use

### Other information

- each caplet contains calcium 165 mg, sodium 3 mg
- store between 20°-25°C (68°-77°F). Protect from light.
- do not use if printed blister unit is broken or torn

\*\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Imodium® Multi-Symptom Relief.  
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## CAREONE DIARRHEA AND GAS CONTROL

loperamide hydrochloride, simethicone tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-772
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	L0R1;2;125
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-772-53	12 in 1 CARTON	01/31/2019	
1		1 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	ANDA209837	01/31/2019	

**Labeler** - American Sales Company (809183973)

Revised: 8/2019

American Sales Company