

**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE- loperamide hydrochloride, simethicone tablet**

**CVS Pharmacy**

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**CVS Pharmacy, Inc. Loperamide Hydrochloride and Simethicone Tablets, 2mg/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
- mucus in the stool
- a history of liver disease

**Ask a doctor or pharmacist before use if you are**

taking antibiotics

**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 blister unit 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

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

See New Warning and Directions

12 CAPLETS\*

\*Capsule-shaped tablets

Actual Size

CVS Health.

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

ANTI-DIARRHEAL / ANTI-GAS



CVS Health™

Compare to the active ingredients in Imodium® Multi-Symptom Relief\*\*  
NDC 69842-807-53

# 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

See New Warning and Directions

12 CAPLETS\*

\*Capsule-shaped tablets



Actual Size



OR153-17-C1

### 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

**As a doctor before use** if you have  
fever ■ mucus in the stool ■ a history of liver disease  
**As a doctor or pharmacist before use** if you are taking antibiotics

**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 rightaway. (1-800-222-1222)

### Drug Facts (continued)

#### Directions

■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea

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

Distributed by: CVS Pharmacy, Inc.  
One CVS Drive, Woonsocket, RI 02895

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**Drug Facts** (continued)**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

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**LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE**

loperamide hydrochloride, simethicone tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-807
<b>Route of Administration</b>	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (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:69842-807-53	12 in 1 CARTON	10/08/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-807-65	1 in 1 CARTON	10/16/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209837	10/08/2018	

**Labeler** - CVS Pharmacy (062312574)

Revised: 10/2018

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