

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE- loperamide hydrochloride, simethicone tablet
CVS Pharmacy

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 right away. (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.

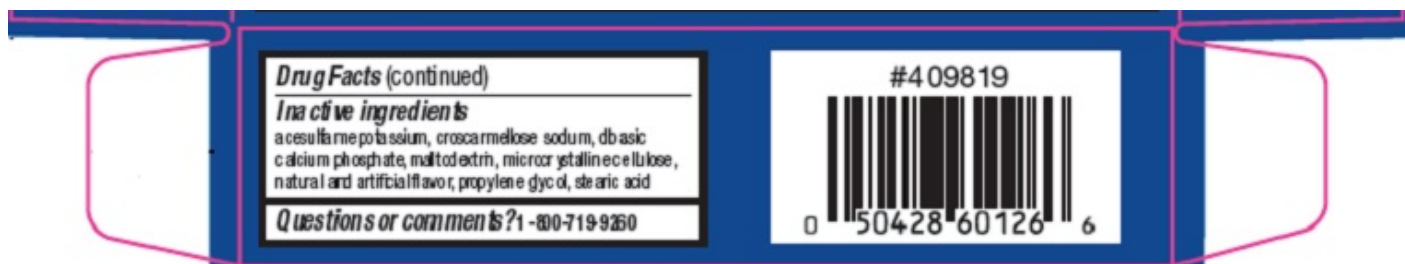
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LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride, simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-807
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

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

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	07/31/2021
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		

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: 12/2022

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