

ANTI DIARRHEAL AND ANTI GAS- loperamide hydrochloride, simethicone tablet
CVS Pharmacy

CVS Pharmacy, Inc. Anti-Diarrheal & Anti-Gas 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 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

Anti-Diarrheal & Anti-Gas

LOPERAMIDE HYDROCHLORIDE & SIMETHICONE TABLETS, 2 mg/125 mg

ANTI-DIARRHEAL/ANTI-GAS

Multi-symptom relief caplet

Relieves symptoms of diarrhea plus:

Cramps & pressure

Bloating

Gas

24 CAPLETS*

*Capsule-shaped tablets

Actual Size

CVS Health.

Anti-Diarrheal & Anti-Gas

LOPERAMIDE HYDROCHLORIDE & SIMETHICONE TABLETS,
2 mg/125 mg

ANTI-DIARRHEAL /ANTI-GAS
Multi-symptom relief caplet

CVS Health.

Compare to the active ingredients in
Imodium® Multi-Symptom Relief**
NDC 69842-644-62

Anti-Diarrheal & Anti-Gas

LOPERAMIDE HYDROCHLORIDE &
SIMETHICONE TABLETS, 2 mg/125 mg

ANTI-DIARRHEAL /ANTI-GAS
Multi-symptom relief caplet

Relieves symptoms of diarrhea *plus*:

- Cramps & pressure
- Bloating
- Gas

24 CAPLETS*

*Capsule-shaped tablets



Actual Size



OR162 17 C1

Drug Facts

Active ingredients (in each caplet) Purpose
Loperamide HCl 2 mg.....Anti-diarrheal
Simethicone 125 mg.....Anti-gas

Uses relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

Warnings

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Heart alert: Taking more than directed can cause serious heart problems or death.

Do not use

- if you have blood 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

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 on case of 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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V-16467

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Drug Facts (continued)

Inactive ingredients acetaminophen, croscarmellose sodium, dibasic calcium phosphate, maltodextrin, microcrystalline cellulose, natural and artificial flavor, polyethylene glycol, stearic acid

#369548





ANTI DIARRHEAL AND ANTI GAS

loperamide hydrochloride, simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-644
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)	
CROSCARMELOSE 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

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:69842-644-62	24 in 1 CARTON	08/06/2019	
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	08/06/2019	

Labeler - CVS Pharmacy (062312574)

Revised: 8/2019

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