

ANTI DIARRHEAL ANTI GAS- loperamide hydrochloride, simethicone tablet
Kroger Company

Kroger Co. 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

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 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?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO the active ingredients of IMODIUM® MULTI-SYMPTOM RELIEF

See side panel

SEE NEW WARNING AND DIRECTIONS

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

Our Pharmacists Recommend

12 CAPLETS*

*Capsule-Shaped Tablets

actual size

Drug Facts (continued)

Warnings: 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 a history of heart disease or if you are taking any medicine that may increase your risk of heart disease. Do not use if you have difficulty swallowing. Ask a doctor before use if you have a fever, muscle pain, a history of liver disease, or a history of kidney disease. When using this product, brush, floss, or use dental floss regularly. Stop use and ask a doctor if you get abdominal swelling or bloating. These may be signs of a serious condition. If pregnant or breastfeeding, 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: See the side panel for full directions.

Directions (continued)

1 caplet (250 mg) 4 times a day with food or 1 caplet 4 times a day with meals and snacks, as directed on the side panel.

Other information:

▲ Each caplet contains: loperamide HCl 2 mg, simethicone 125 mg. **Keep out of reach of children.** If you are taking other medicine, ask a doctor before use. Do not use if you have a fever, muscle pain, a history of liver disease, or a history of kidney disease. Do not use if you have difficulty swallowing. Ask a doctor before use if you have a history of heart disease or if you are taking any medicine that may increase your risk of heart disease. When using this product, brush, floss, or use dental floss regularly. Stop use and ask a doctor if you get abdominal swelling or bloating. These may be signs of a serious condition. If pregnant or breastfeeding, 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)

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QUALITY GUARANTEE
www.kroger.com

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Kroger

Loperamide Hydrochloride and Simethicone
Tablets, 2 mg/125 mg

Anti-Diarrheal+Anti-Gas

MULTI-SYMPTOM RELIEF CAPLET

COMPARE TO the active ingredients of IMODIUM[®]
MULTI-SYMPTOM RELIEF **See side panel

SEE NEW WARNING AND DIRECTIONS

NDC 30142-581-53

Kroger

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

12 CAPLETS*
*Capsule-Shaped Tablets



QUALITY GUARANTEE
www.kroger.com

OR153 45 C1

ANTI DIARRHEAL ANTI GAS

loperamide hydrochloride, simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-58 1
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:30 142-58 1-53	12 in 1 CARTON	04/24/20 19	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30 142-58 1-62	24 in 1 CARTON	02/07/20 20	
2		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	04/24/2019	

Labeler - Kroger Company (006999528)

Revised: 2/2020

Kroger Company