

**GOOD SENSE ANTI DIARRHEAL ANTI GAS- loperamide hydrochloride, simethicone tablet
L. Perrigo Company**

Perrigo 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 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

Multi-Symptom Relief Caplet

See New Warning and Directions

Loperamide Hydrochloride and Simethicone Tablets, 2mg/125mg

Anti-Diarrheal/Anti-Gas

Actual Size

Relieves symptoms of diarrhea plus

Cramps & Pressure – Bloating – Gas

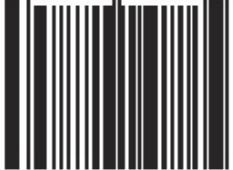
Compare to active ingredients of Imodium® Multi-Symptom Relief

100% SATISFACTION GUARANTEED

18 Caplets*

*Capsule-Shaped Tablets

3 0113-1087-89 3



Gluten Free

Questions or comments? 1-800-79-9280

Drug Facts (continued)
 Inactive ingredients: calcium phosphate, croscarmellose sodium, dicalcium phosphate, microcrystalline cellulose, calcium phosphate, croscarmellose sodium, dicalcium phosphate, microcrystalline cellulose, natural and artificial flavors, polyethylene glycol, stearic acid

Drug Facts (continued)
Directions
 • Drink plenty of clear fluids to help prevent dehydration.
 • Take on an empty stomach (1 hour before or 2 hours after a meal).
 • Take with a full 8 oz (240 mL) glass of water.
 • If not right dose on chart below, if possible, use weight to dose, otherwise, use age.

Adults and over 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; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
Children 6-8 years (40-50 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
Children 2-5 years (24 to 47 lbs)	ask a doctor
Children under 2 years (up to 33 lbs)	do not use

Other information
 • Each caplet contains: calcium 16.5 mg, sodium 3 mg
 • Store between 20°-25°C (68°-77°F). Protect from light.
 • Do not use if prints blisters are broken or torn.

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 blood in or black stool.
 If you have difficulty swallowing.
 Ask a doctor before use if you have a history of liver disease, muscle in the stomach, or a history of the disease.
 Ask a doctor or pharmacist before use if you are taking antibiotics.
 When using this product, avoid alcohol, dizziness, or lightheadedness may occur. Be careful when driving or operating machinery.
 Stop use and ask a doctor if:
 • Symptoms get worse or last for more than 2 days.
 • You get abdominal swelling or bloating. These may be signs of a serious condition.
 • You have difficulty swallowing the caplet.
 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)

Distributed by **Perrigo**® Allergan, MI 49010

CODE AREA

OR180 C2 C1

GOODSENSE®

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

Anti-Diarrheal/Anti-Gas

GOODSENSE®

NDC 0113-1087-89

Multi-Symptom Relief Caplet

See New Warning and Directions

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

Anti-Diarrheal/Anti-Gas



Actual Size

Relieves symptoms of diarrhea **plus**
 • Cramps & Pressure • Bloating • Gas

18 Caplets*

Compare to active ingredients of **Imodium® Multi-Symptom Relief**



100% SATISFACTION GUARANTEED

GOOD SENSE ANTI DIARRHEAL ANTI GAS

loperamide hydrochloride, simethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-1087
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:0113-1087-89	18 in 1 CARTON	01/29/2019	
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	01/29/2019	

Labeler - L. Perrigo Company (006013346)

Revised: 2/2019

L. Perrigo Company