

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE- loperamide hydrochloride and simethicone tablet
Granules India Ltd

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg

SPL UNCLASSIFIED SECTION

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 ag

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; $\frac{1}{2}$ 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; $\frac{1}{2}$ 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 148.40 mg, sodium 1.40 mg**
- store between 20-25°C (68-77°F). Protect from light.
- **for blister: do not use if blister unit is torn or broken**

Inactive Ingredients

acesulfame potassium, anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, flavor, microcrystalline cellulose, stearic acid.

Questions or comments?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

Manufactured by:

Granules India Limited

Hyderabad-500 081, INDIA

MADE IN INDIA

PRINCIPAL DISPLAY PANEL

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**

NDC 62207-739-69

Loperamide Hydrochloride and Simethicone Tablets

2 mg/125 mg per caplet

Multi-Symptom Relief Caplets

Antidiarrheal/Anti-Gas

Peel off the foil. Gently push tablet out.

Mfg. by: Granules India Limited

Made in India

LOT#

EXP. DATE:



37/RR/AP/2003/F/R



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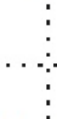
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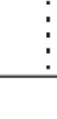
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** This product is not manufactured or distributor by
 Johnson and Johnson Consumer Inc., distributor of
 Imodium® Multi-Symptom Relief.

R 06/2021 2000000XXXX
 37/RR/AP/2003/F/R

Drug Facts	Drug Facts (continued)						
<p>Active ingredients (in each caplet) Purposes Loperamide HCl, 2 mg.....Anti-diarrheal Simethicone, 125 mgAnti-gas</p> <p>Uses relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas</p> <p>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</p> <p>Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease ■ a history of abnormal heart rhythm</p> <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.</p> <p>When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.</p> <p>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 →</p>	<p>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)</p> <p>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.</p> <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours</td> </tr> <tr> <td>children 9-11 years (60-95 lbs)</td> <td>1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours</td> </tr> <tr> <td>children 6-8 years (48-59 lbs)</td> <td>1 caplet after the first loose stool; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours</td> </tr> </table>	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
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Un varnish coding details

children 2-5 years (34 to 47 lbs)	ask a doctor	<ul style="list-style-type: none"> store between 20-25°C (68-77°F). Protect from light. do not use if blister unit is torn or broken
children under 2 years (up to 33 lbs)	do not use	
<p>Other information ■ each caplet contains: calcium 148.40 mg, sodium 1.40 mg →</p>		<p>Inactive ingredients acesulfame potassium, anhydrous dibasic calcium phosphate, colloidal silicon dioxide, croscarmellose sodium, flavor, microcrystalline cellulose, stearic acid. ↓</p>

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12 Caplets *
 *capsule-shaped tablets

****Compare to the active ingredients in Imodium® Multi-Symptom Relief**

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 2 mg/125 mg



LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE			
loperamide hydrochloride and simethicone tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-739
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white (off white)	Score	2 pieces
Shape	CAPSULE (Capsule shaped tablet)	Size	17mm
Flavor	VANILLA	Imprint Code	I;9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-739-69	2 in 1 CARTON	03/01/2023	
1		6 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	ANDA215981	03/01/2023	

Labeler - Granules India Ltd (915000087)