

**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



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



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



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



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

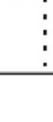
Made in India

LOT#

EXP. DATE:



37/RR/AP/2003/F/R



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



**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

\*\* 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><b>Active ingredients (in each caplet) Purposes</b>            Loperamide HCl, 2 mg.....Anti-diarrheal            Simethicone, 125 mg .....Anti-gas</p> <p><b>Uses</b> relieves symptoms of diarrhea plus bloating,            pressure and cramps, commonly referred to as gas</p> <p><b>Warnings</b>  <b>Allergy alert:</b> Do not use if you have ever had a            rash or other allergic reaction to loperamide HCl  <b>Heart alert:</b> Taking more than directed can cause            serious heart problems or death  <b>Do not use</b> ■ if you have bloody or black stool            ■ if you have difficulty swallowing</p> <p><b>Ask a doctor before use if you have</b>            ■ fever            ■ mucus in the stool            ■ a history of liver disease            ■ a history of abnormal heart rhythm</p> <p><b>Ask a doctor or pharmacist before use if you are</b>            taking a prescription drug. Loperamide may            interact with certain prescription drugs.</p> <p><b>When using this product</b> tiredness, drowsiness or            dizziness may occur. Be careful when driving or            operating machinery.</p> <p><b>Stop use and ask a doctor if</b>            ■ 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.  <b>Keep out of reach of children.</b> In case of overdose,            get medical help or contact a Poison Control            Center right away. (1-800-222-1222)</p> <p><b>Directions</b>            ■ 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
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						

Un varnish coding details

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

2000000XXXX

**Loperamide Hydrochloride and  
 Simethicone Tablets**  
**2 mg/125 mg**

NDC 62207-739-69

**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

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



<b>LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE</b>			
loperamide hydrochloride and simethicone tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62207-739
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

**Product Characteristics**

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

**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)