

IMODIUM MULTI-SYMPTOM RELIEF- loperamide hydrochloride and dimethicone tablet
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

IMODIUM

Multi-Symptom Relief

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purposes</i>
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

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 blister unit is torn or broken**

Inactive ingredients

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

NDC 50580-338-61

Imodium[®]

Loperamide HCl, 2 mg /Simethicone, 125 mg Antidiarrheal/Anti-gas

Multi-Symptom Relief

Caplet

Relieves symptoms
of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

24 Caplets*

*capsule-shaped tablets

Actual Size



Drug Facts (continued)
Inactive Ingredients
 capramide sodium, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid
 Call 1-877-895-3665 (for help) or 1-877-895-3665 (collect)
Questions or comments?

Drug Facts (continued)

Purposes
 Loperamide HCl 2 mg
 Simethicone 125 mg
 Anti-diarrheal
 Anti-gas

Directions
 Take only on an empty stomach (1 hour before or 2 hours after a meal).
 Take with a full glass of water.
 Drink plenty of clear fluids to help prevent dehydration.
 If pregnant or breastfeeding, ask a health professional for advice.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately. (1-800-222-1222)

Warnings
 Do not use if you have blood or stool problems or death.
 Heart failure: Taking more than directed can cause serious heart problems or death.
 Allergies: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.
 Do not use if you have had blood or stool problems or death.
 Ask a doctor before use if you have a history of heart disease or if you have had a heart attack or stroke.
 Ask a doctor or pharmacist before use if you are taking a prescription drug, especially one for the heart.
 When using this product, dizziness or weakness may occur because of the ingredients.
 Stop use and ask a doctor if you experience dizziness or weakness or if you are taking a prescription drug, especially one for the heart.
 Ask a doctor or pharmacist before use if you are taking a prescription drug, especially one for the heart.
 Ask a doctor before use if you have a history of heart disease or if you have had a heart attack or stroke.
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 When using this product, dizziness or weakness may occur because of the ingredients.
 Stop use and ask a doctor if you experience dizziness or weakness or if you are taking a prescription drug, especially one for the heart.

Other Information
 Each caplet contains 2 mg loperamide HCl and 125 mg simethicone.
 Each caplet contains 2 mg loperamide HCl and 125 mg simethicone.
 Do not use if blister unit is torn or broken.



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 Fort Washington, PA 19034 USA
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Imodium
 How can we help?
 1-877-895-3665

30048691

Imodium[®]

Loperamide HCl, 2 mg/Simethicone, 125 mg Antidiarrheal/Anti-gas

Multi-Symptom Relief
 Caplet

Relieves symptoms of diarrhea **plus**

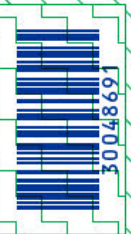
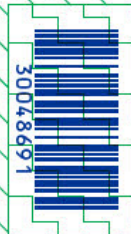
- Cramps & Pressure
- Bloating
- Gas

24 Caplets*



*capsule-shaped tablets

Actual Size



NDC 50580-338-61



IMODIUM MULTI-SYMPTOM RELIEF

loperamide hydrochloride and dimethicone tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-338
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	16mm
Flavor		Imprint Code	IMO;2;125
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-338-12	2 in 1 CARTON	07/01/2008	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-338-18	3 in 1 CARTON	07/01/2008	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-338-42	1 in 1 CARTON	07/01/2008	09/07/2021
3		42 in 1 BOTTLE; Type 0: Not a Combination Product		

4	NDC:50580-338-30	1 in 1 CARTON	07/01/2008	09/07/2021
4		30 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:50580-338-60	2 in 1 PACKAGE	06/14/2013	07/31/2021
5		1 in 1 CARTON		
5		30 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:50580-338-61	4 in 1 CARTON	06/24/2019	
6		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
NDA	NDA021140	07/01/2008	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 10/2022

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division