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

IMODIUM

Multi-Symptom Relief

Drug Facts

Active ingredients (in each caplet)	Purposes
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

See New Warning and Directions

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 & PressureBloating
- Gas

24 Caplets*

*capsule-shaped tablets Actual Size

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Drug Facts (continued)



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Drug Facts (continued)

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Drug Facts

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
JOHNSON & JOHNSON CONSUMER INC.
MCNeil Consumer Healthcare Division
For tWashington, PA 19034 USA

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www.imodium.com

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Imodium

How can we help? *(*, 1-877-895-3665

See New Warning and Directions

NDC 50580-338-61

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

Multi-Symptom Relief Caplet

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas



*capsule-shaped tablets

ActualSize







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)	Dime thic one	125 mg

Inactive Ingredients				
Ingredient Name	Strength			
acesulfame potassium (UNII: 23OV73Q5G9)				
croscarmellose sodium (UNII: M28OL1HH48)				
dibasic calcium phosphate dihydrate (UNII: O7TSZ97GEP)				
microcrystalline cellulose (UNII: OP1R32D61U)				
stearic acid (UNII: 4ELV7Z65AP)				

Product Characteristics					
Color	WHITE	Score	2 pieces		
Shape	OVAL	Size	16 mm		
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		
3		42 in 1 BOTTLE; Type 0: Not a Combination Product			
4	NDC:50580-338-30	1 in 1 CARTON	07/01/2008		
4		30 in 1 BOTTLE; Type 0: Not a Combination Product			
5	NDC:50580-338-60	2 in 1 PACKAGE	06/14/2013		
5	NDC:50580-338-30	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		

 $\pmb{Labeler} \textbf{-} Johnson \& Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)$

Revised: 6/2019 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division