IMODIUM MULTI-SYMPTOM RELIEF- loperamide hydrochloride and dimethicone tablet
Johnson & Johnson Consumer Inc.

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

NDC 50580-338-12

Imodium ®

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

Multi-Symptom Relief

Caplet

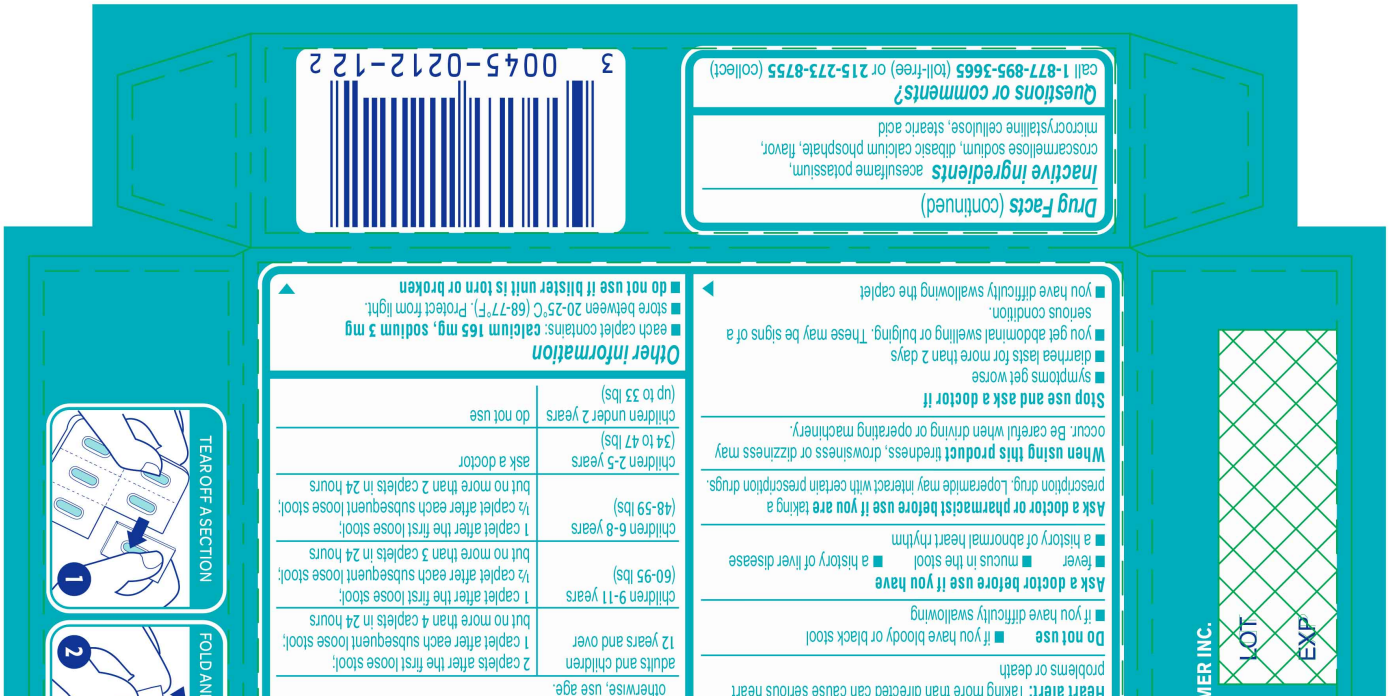
Relieves symptoms
of diarrhea *plus*

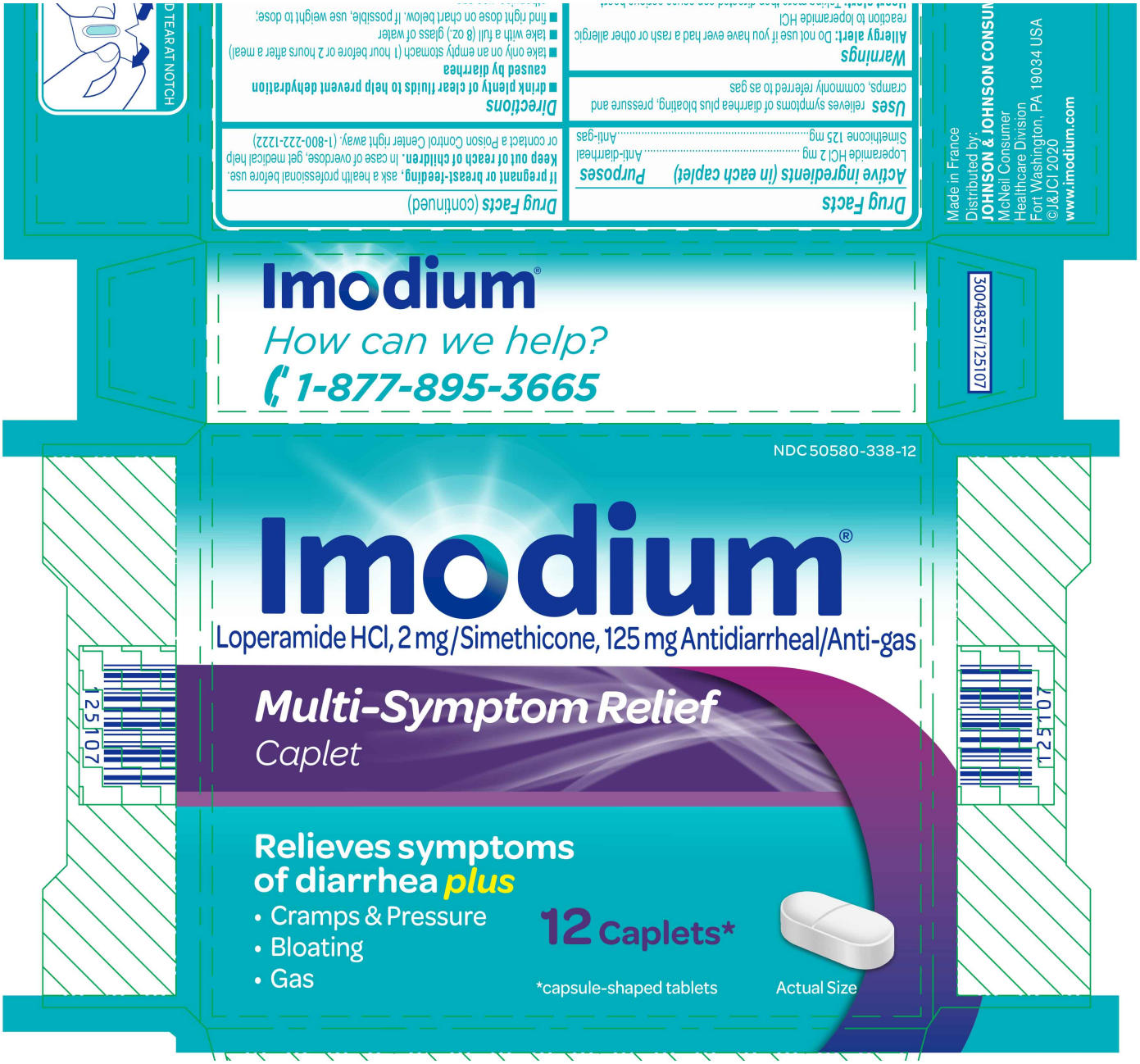
- Cramps & Pressure
- Bloating
- Gas

12 Caplets*

*capsule-shaped tablets

Actual Size





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		
7	NDC:50580-338-64	4 in 1 CARTON	02/26/2024	
7		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. (878046358)

Revised: 5/2024 Johnson & Johnson Consumer Inc.