

**IMODIUM A-D- loperamide hydrochloride tablet, film coated**  
**Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division**

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**Imodium®**  
**A-D**

***Drug Facts***

**Active ingredient (in each caplet)**

Loperamide HCl 2 mg

**Purpose**

Anti-diarrheal

**Use**

controls symptoms of diarrhea, including Travelers' Diarrhea

**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

**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.

**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**
- find right dose on chart. 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; 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; 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**

- store at 20°-25°C (68°-77°F)
- **do not use if blister unit is broken or torn**

**Inactive ingredients**

anhydrous lactose, carnauba wax, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

**Questions or comments?**

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

**PRINCIPAL DISPLAY PANEL**

See New Warnings

NDC 50580-317-06

Imodium®

A-D

Loperamide Hydrochloride Tablets, 2mg

Anti-Diarrheal

Anti-Diarrheal

Caplets

Controls the symptoms  
of diarrhea

Actual Size

\*Capsule-Shaped Tablets

12 Caplets\*

**CODE AREA**

7N253 MN C2

**Drug Facts**

**Active ingredient** (in each caplet)  
Loperamide HCl 2 mg.....Anti-diarrheal

**Purpose**  
Use controls symptoms of diarrhea, including Traveler's Diarrhea

**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  
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. If pregnant or breast-feeding, ask a health professional before use.

**Drug Facts (continued)**  
anhydrous lactose, carnauba wax, hypromellose, magnesium stearate, croscarmellose sodium, polyethylene glycol, pregelatinized starch

**Drug Facts (continued)**  
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**  
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**Drug Facts (continued)**  
**Questions or comments?**  
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Active ingredient made in Italy  
Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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30046162



See New Warnings NDC 50580-317-06

**Imodium®**  
**A-D** Loperamide Hydrochloride Tablets, 2mg  
Anti-Diarrheal

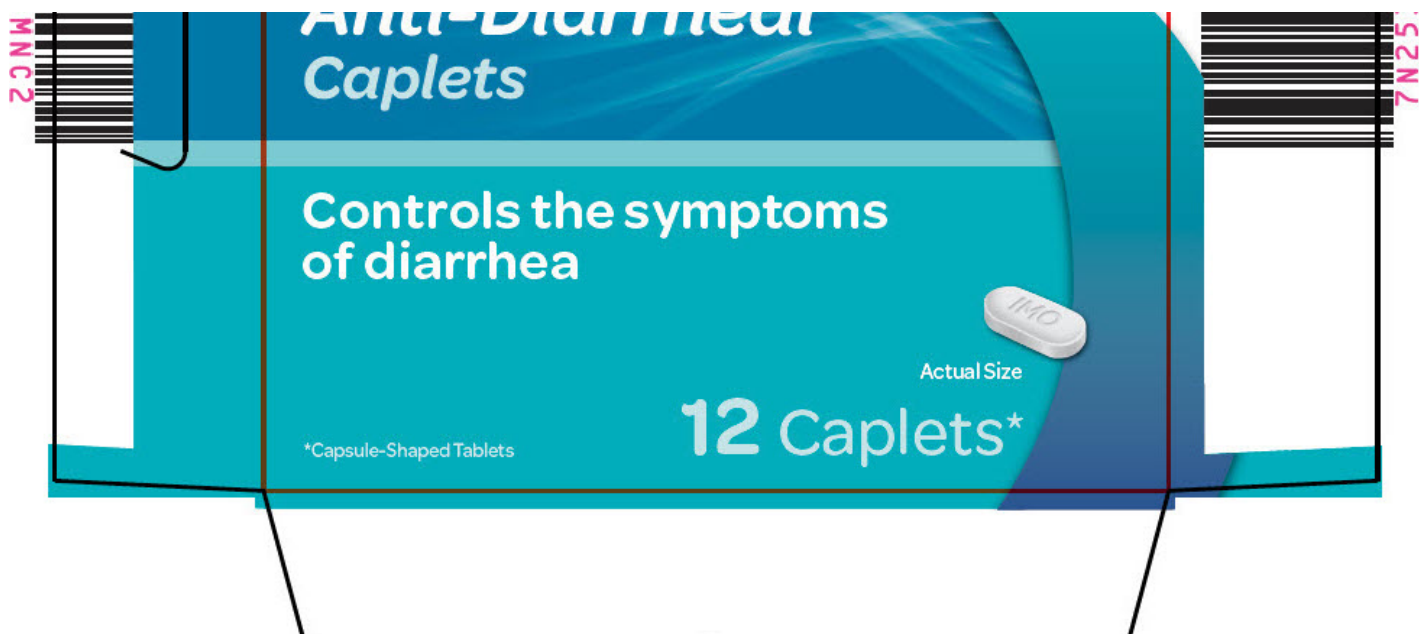
1. Tear off a section  
2. Tear at notch. Use scissors if necessary



How can we help?  
1-877-895-3665

7N253

3MNC2



## IMODIUM A-D

loperamide hydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50580-317
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Loperamide hydrochloride (UNII: 77TB5393C) (Loperamide - UNII:6X9OC3H4II)	Loperamide hydrochloride	2 mg

### Inactive Ingredients

Ingredient Name	Strength
anhydrous lactose (UNII: 3SY5LH9PMK)	
carnauba wax (UNII: R12CBM0EIZ)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	IMO;2;MG
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-317-01	1 in 1 CARTON	07/13/2015	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-317-03	4 in 1 CARTON	07/13/2015	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-317-04	6 in 1 CARTON	07/13/2015	12/31/2018
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:50580-317-05	8 in 1 CARTON	07/13/2015	
4		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:50580-317-06	2 in 1 CARTON	02/10/2020	
5		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	ANDA075232	07/13/2015	

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

Revised: 1/2020

Johnson &amp; Johnson Consumer Inc., McNeil Consumer Healthcare Division