

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

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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

NDC 50580-317-06

Imodium<sup>®</sup>

A-D

Loperamide Hydrochloride Tablets, 2mg  
Anti-Diarrheal

Anti-Diarrheal  
Caplets

Controls the symptoms  
of diarrhea

Actual Size

\*Capsule-Shaped Tablets

12 Caplets\*

7N253 MIN C3

**Drug Facts (continued)**

**Inactive ingredients**  
anhydrous lactose, camouba wax, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

**Drug Facts (continued)**

**Questions or comments?**  
1-877-895-3665 (toll-free) or 215-273-8755 (collect)

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

**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.

**When using this product** tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

**Ask a doctor or pharmacist before use if you are taking a prescription drug.** Loperamide may interact with certain prescription drugs.

**Ask a doctor before use if you have**  
■ fever  
■ mucus in the stool  
■ a history of liver disease  
■ a history of abnormal heart rhythm

**Do not use if you have** bloody or black stool

**Heart alert:** Taking more than directed can cause serious heart problems or death

**Warnings**  
**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

**Use** controls symptoms of diarrhea, including Travelers' Diarrhea

Loperamide HCl 2 mg.....Anti-diarrheal

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

**Drug Facts**

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

**children**  
under 2 years do not use

**children**  
2-5 years (34 to 47 lbs) ask a doctor

**children**  
6-8 years (48-59 lbs) 1 caplet after the first dose; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours

**children**  
9-11 years (60-95 lbs) 1 caplet after the first dose; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours

**children**  
12 years and over 2 caplets after the first dose; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours

**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.

**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).

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



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

Active ingredient made in Italy  
Distributed by:  
**JOHNSON & JOHNSON CONSUMER INC.**  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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30048667



NDC 50580-317-06

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

7N253

7N253



## 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
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (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	10/31/2021
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. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.