### 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 HCI

#### **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 ® A-D

Loperamide Hydrochloride Tablets, 2mg Anti-Diarrheal

Anti-Diarrheal Caplets

Controls the symptoms of diarrhea

**Actual Size** 

\*Capsule-Shaped Tablets

12 Caplets\*

glycol, pregelatinized starch microcrystalline cellulose, polyetnyl ene hypromellose, magnæium stearate, anhydrous lactose, camaubawax, stn eib ergni evit əsnl

Drug Facts (continued)

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Loperamide HG 2 mg. .. (in e ach caplet) Active ingredient

Drug Facts

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

Active ingredient made in Italy

JOHNSON & JOHNSON CONSUMER INC.

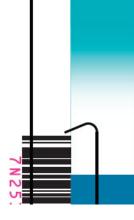
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NDC 50580-317-06

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A-D Loperamide Hydrochloride Tablets, 2mg
Anti-Diarrheal



7N253 MN C3



#### IMODIUM A-D

loperamide hydrochloride tablet, film coated

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDW1A)

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Prod	 Infa	4444	1

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-317

Route of Administration ORAL

## Active Ingredient/Active Moiety Ingredient Name Basis of Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - LOPERAMIDE - 2 mg

LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - LOPERAMIDE HYDROCHLORIDE LOPERAMIDE HYDROCHLORIDE

# 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)

Product Characteristics				
Color	white	Score	2 pieces	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	IMO;2;MG	
Contains				

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.