IMODIUM A-D- loperamide hydrochloride capsule, liquid filled Johnson & Johnson Consumer Inc.

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#### Imodium A-D

Drug Facts

#### Active ingredient (in each capsule)

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
- in children under 12 years of age

#### 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.

# 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

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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.

# Directions

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- not for use in children under 12 years of age
- adults and children 12 years and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours

# Other information

- store at 20°-25°C (68°-77°F). Protect from light.
- avoid excessive heat above 40°C (104°F)
- do not use if blister unit is torn or broken

#### Inactive ingredients

butylated hydroxyanisole, edible ink, FD&C blue no. 1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water

#### **Questions or comments?**

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

# PRINCIPAL DISPLAY PANEL

NDC 50580-367-02

Imodium<sup>®</sup>

# A-D

Loperamide HCl, 2mg/Anti-Diarrheal

Soft Gelatin Capsules

#### Anti-Diarrheal Softgels

# Controls the symptoms of diarrhea

Suitable for adults and

children 12 years and over

# 24 Softgels\*

Actual Size

\*each liquid-filled capsule contains 2 mg loperamide HCl

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	<b>In active ingredients</b> butylated hydroxyanisole, edible ink, FD&C blue no. 1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, punified water	e ingredi Ibuted by <b>NSON &amp;</b> eil Consu
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	<mark>II pregnant or breast-feeding</mark> , ask a heath professional before use. <b>Keep out of reach of children</b> . In case of overdose, get medical help or contact a Poison Control Center right away.	NC.
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# IMODIUM A-D loperamide hydrochloride capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:50580-367 Route of Administration ORAL ORAL V Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
WATER (UNII: 059QF0KO0R)		

#### **Product Characteristics**

Color	blue (Light blue)	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	IMO
Contains			

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580- 367-01	1 in 1 CARTON	07/11/2016	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580- 367-02	2 in 1 CARTON	07/11/2016	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
NDA	NDA021855	07/11/2016	

# Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.