

ANTI-DIARRHEAL- loperamide hydrochloride tablet
IMO-GEN LABS LLC

ANTI-DIARRHEAL

Loperamide Hydrochloride Caplets, 2 mg

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 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 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 (1-800-222-1222) right away.

Directions

- **drink plenty of clear liquid 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 (34-47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- store between 20° and 25°C (68° and 77°F)

Inactive ingredients

corn starch, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue#1 brilliant blue, magnesium stearate, microcrystalline cellulose, silica gel

Questions?

call toll-free 1-866-933-6337

Distributed by:

IBS LABS

Wilmington, DE 19801

Principal Display Panel

Compare to the active ingredient in **Imodium® A-D †**

Anti-Diarrheal

Loperamide Hydrochloride Caplets, 2 mg

Controls Symptoms of Diarrhea

†This product is not manufactured or distributed by the owner of the registered trademark Imodium® A-D.

Compare to the active ingredient in **Imodium® A-D†**

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01000 27811
9

DBS LABS

ORIGINAL PRESCRIPTION STRENGTH

ANTI-DIARRHEAL

LOPERAMIDE HYDROCHLORIDE CAPLETS, 2 MG

VALUE SIZE

96

CAPLETS

CONTROLS SYMPTOMS OF DIARRHEA

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

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

PEEL FOR DIRECTIONS 67811-096-111-1

LIFT HERE

Drug Facts (continued)

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 (1-800-222-1222) right away.

Directions ■ **drink plenty of clear liquids to help prevent dehydration caused by diarrhea**

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Other information

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Inactive ingredients

corn starch, D&C yellow #10 aluminum lake, dicalcium phosphate dihydrate, FD&C blue #1 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel

Questions? call toll-free 1-866-933-6337

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Distributed by:
DBS LABS
Wilmington, DE 19801

Available at
 www.springmeds.com

Compare to the active ingredient in **Imodium® A-D†**

8
01000 27811
6

DBS LABS

ORIGINAL PRESCRIPTION STRENGTH

ANTI-DIARRHEAL

LOPERAMIDE HYDROCHLORIDE CAPLETS, 2 MG

VALUE SIZE

200

CAPLETS

CONTROLS SYMPTOMS OF DIARRHEA

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

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

PEEL FOR DIRECTIONS 67811-200-111-1

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health	of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	liquids to help prevent dehydration caused by diarrhea	e, use
first loose stool; but no more than 4 caplets in 24 hours	first loose stool; but no more than 3 caplets in 24 hours	first loose stool; but no more than 2 caplets in 24 hours	
ask a doctor	do not use		
77°F)			
um lake, FD&C blue #1 brilliant blue lake, magnesium stearate,			
933-6337			
led by the owner of the registered trademark Imodium® A-D.			

ANTI-DIARRHEAL		
loperamide hydrochloride tablet		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:84441-711
Route of Administration	ORAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength

Drug Facts (continued)

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 (1-800-222-1222) right away.

Directions ■ **drink plenty of clear liquids to help prevent dehydration caused by diarrhea** ■ find the right dose on chart. If possible, use weight to dose; otherwise, use age.

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Other information

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Inactive ingredients

corn starch, D&C yellow #10 aluminum lake, dicalcium phosphate dihydrate, FD&C blue #1 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel

Questions? call toll-free 1-866-933-6337

†This product is not manufactured or distributed by the owner of the registered trademark Imodium® A-D.

Distributed by:
LOPERAMAX
 Wilmington, DE 19801
Available at


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Compare to the active ingredient in Imodium® A-D:

ORIGINAL PRESCRIPTION STRENGTH

LOPERAMAX

ANTI-DIARRHEAL

LOPERAMIDE HYDROCHLORIDE 2 MG

CONTROLS SYMPTOMS OF DIARRHEA

VALUE SIZE
250
 CAPLETS



MADE IN USA

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

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

Use controls symptoms of diarrhea, including Travelers' Diarrhea

Warnings

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Ask a doctor 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.

PEEL FOR DIRECTIONS 67811-250-112-0

LIFT HERE

Drug Facts (continued)

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 (1-800-222-1222) right away.

Directions ■ **drink plenty of clear liquids to help prevent dehydration caused by diarrhea** ■ find the right dose on chart. If possible, use weight to dose; otherwise, use age.

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Other information

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Inactive ingredients

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Questions? call toll-free 1-866-933-6337

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Distributed by:
DBS LABS
 Wilmington, DE 19801
Available at


LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)		LOPERAMIDE HYDROCHLORIDE	2 mg	
Inactive Ingredients				
Ingredient Name			Strength	
STARCH, CORN (UNII: O8232NY3SJ)				
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)				
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Product Characteristics				
Color	green	Score	2 pieces	
Shape	OVAL	Size	10mm	
Flavor		Imprint Code	44;375	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84441-711-96	96 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	
2	NDC:84441-711-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	
3	NDC:84441-711-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2026	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076497	01/01/2024		

Labeler - IMO-GEN LABS LLC (119282683)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(84441-711) , label(84441-711) , pack(84441-711)