

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.

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



IBS 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 (continued)

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

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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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IBS LABS
Wilmington, DE 19801

Available at
 wellspringmeds.com

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 G7811-200-111-0

LIFT HERE

Drug Facts (continued)

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

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PEEL FOR DIRECTIONS G7811-096-111-0

LIFT HERE

9 118Z 01009 8



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



IBS 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

Use controls symptoms of diarrhea, including Travelers' Diarrhea

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■ a history of abnormal heart rhythm

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PEEL FOR DIRECTIONS G7811-096-111-0

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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
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	

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)

Revised: 1/2024

IMO-GEN LABS LLC