

ANTI-DIARRHEAL- loperamide hcl tablet
GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.

Healthcare 44-375-Delisted

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

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

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 (34-47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- store between 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**

Inactive ingredients

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

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal Display Panel

HEALTHCARE™

NDC 64092-105-12

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

Anti-Diarrheal

*Loperamide HCl Tablets, 2 mg
Anti-diarrheal*

Controls the Symptoms of Diarrhea

Actual Size

12 CAPLETS

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Imodium® A-D. 50844 REV0619M37502

1. To open, tear at perforations and remove a section.
2. Use scissors to cut through plastic for caplet.

HEALTHCARE GUARANTEE

If you are not completely satisfied with this product, regardless of reason, return your unused portion to Great Lakes Wholesale for a full refund

Distributed By: Great Lakes Wholesale & Marketing L.L.C.
3729 Patterson Ave. S.E., Grand Rapids, MI 49512
www.glwholesale.com

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
Active ingredient (in each caplet) Loperamide HCl 2 mgAnti-diarrheal
Purpose Anti-diarrheal
Use controls symptoms of diarrhea, including Travelers' Diarrhea

HEALTHCARE

NDC 64002-105-12
 Compare to the active ingredient in Imodium® A-D*

Anti-Diarrheal

Loperamide HCl Tablets, 2 mg

Anti-diarrheal

Controls the Symptoms of Diarrhea



12 CAPLETS

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 3729 Palerston Ave. S.E., Grand Rapids, MI 49512
 www.glwholesale.com



2. Use $\frac{3}{8}$ " to cut through plastic for caplet.



1. To open, tear at perforations and remove a section.



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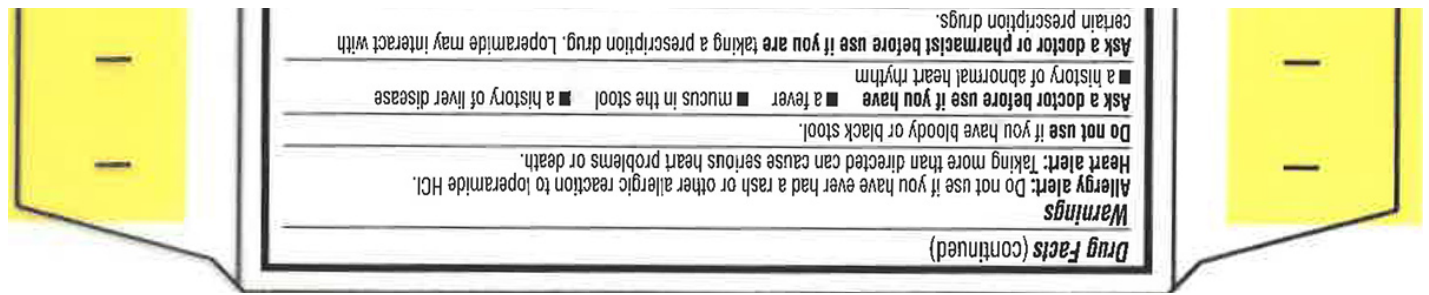
HEALTHCARE GUARANTEE
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Drug Facts (continued)
TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
Inactive ingredients corn starch, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide
Questions or comments? Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

B-0616-375-02
 REV0619M37502

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 bloating. 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 fluids to help prevent dehydration caused by diarrhea ■ find right dose on chart. If possible, use weight to dose; otherwise, use age.
Other information ■ store between 20°-25°C (68°-77°F) ■ see end flap for expiration date and lot number

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HealthCare 44-375

ANTI-DIARRHEAL

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-105
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:64092-105-12	2 in 1 CARTON	05/03/2005	10/14/2024
1		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	ANDA076497	05/03/2005	10/14/2024

Labeler - GREAT LAKES WHOLESAL, MARKETING, & SALES, INC. (361925498)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(64092-105) , pack(64092-105)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(64092-105)

Revised: 9/2023

GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.