

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

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**Healthcare 44-375**

***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.

**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

**Ask a doctor or pharmacist before use if you are**

taking antibiotics.

**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 under 6 years (up to 47 lbs)	ask a doctor

### ***Other information***

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

### ***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 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 McNeil Consumer Healthcare, owner of the registered trademark Imodium® A-D.

50844 REV0715K37502

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 mg.

**Purpose**  
Anti-diarrheal

**Use**  
controls symptoms of diarrhea, including Travelers' Diarrhea

# 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

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

2. Use  $\frac{1}{2}$  to cut through plastic for caplet.



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**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

OMIT A

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

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**Drug Facts (continued)**

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

**Other information**

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

■ see end flap for expiration date and lot number ■ store between 20°-25°C (68°-77°F)

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 under 6 years (up to 47 lbs)	ask a doctor

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REV0715K37502

**Drug Facts (continued)**

**Warnings**  
 Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.  
 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

Ask a doctor or pharmacist before use if you are taking antibiotics.

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

Healthcare 44-375

## ANTI-DIARRHEAL

loperamide hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64092-105
<b>Route of Administration</b>	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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	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	
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	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(64092-105)

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(64092-105)

Revised: 1/2017

GREAT LAKES WHOLESAL, MARKETING, & SALES, INC.