

ANTI-DIARRHEAL- loperamide hcl tablet
L.N.K. International, Inc.

Quality Plus 44-375 Anti-diarrheal

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 (37-47 lbs)	ask a doctor
children under 2 years (up to 30 lbs)	do not use

Other information

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

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

**QUALITY
+ PLUS**

NDC 50844-375-08

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

**ANTI-
DIARRHEAL
Loperamide HCl Tablets, 2 mg**

ANTI-DIARRHEAL

Controls the symptoms of diarrhea

24 Caplets

Actual Size

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

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

50844 REV0619D37508

Distributed by

LNK INTERNATIONAL, INC.

60 Arkay Drive

Hauppauge, NY 11788

USA

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

Inactive ingredients corn starch, D&C yellow #10 aluminum lake, docusate calcium phosphatate hydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

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

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.

Drug Facts (continued)
 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, drowsiness, dizziness, 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.

Drug Facts
Active ingredient (in each caplet)
 Loperamide HCl 2 mg
 Purpose Anti-diarrheal

Use
 Use to control symptoms of diarrhea, including Traveler's Diarrhea

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

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

B-1603-375-08-R
 REV0619037508

NDC 50844-375-08


 *Compare to active ingredient in Imodium® A-D

ANTI-DIARRHEAL

Loperamide HCl Tablets, 2 mg

ANTI-DIARRHEAL

QUALITY PLUS

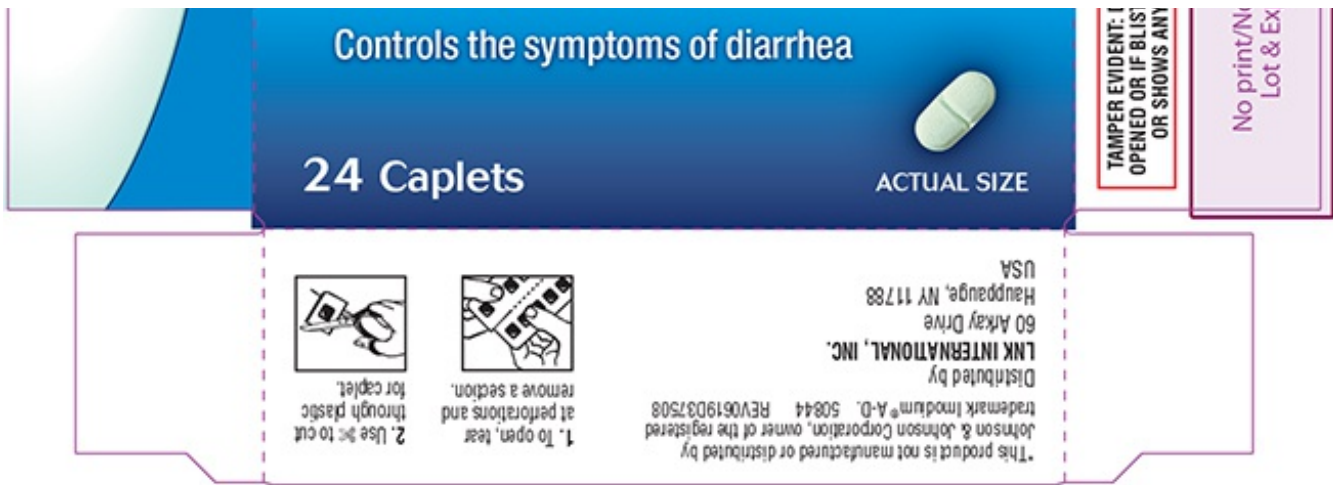
ANTI-DIARRHEAL

Loperamide HCl Tablets, 2 mg



DO NOT USE IF PACKAGE IS
 TORN OR UNIT IS BROKEN
 (SIGNS OF TAMPERING)

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 p date



Quality Plus 44-375

ANTI-DIARRHEAL

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50844-375
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 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product Characteristics

Color	GREEN (light)	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:50844-375-02	3 in 1 CARTON	05/03/2005	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50844-375-08	4 in 1 CARTON	05/03/2005	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50844-375-45	1 in 1 CARTON	05/03/2005	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:50844-375-00	8 in 1 CARTON	05/03/2005	
4		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:50844-375-95	2 in 1 CARTON	05/03/2005	
5		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:50844-375-22	1 in 1 CARTON	05/03/2005	
6		48 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:50844-375-23	1 in 1 CARTON	05/03/2005	
7		72 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:50844-375-46	1 in 1 CARTON	05/03/2005	
8		96 in 1 BOTTLE, PLASTIC; 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 - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(50844-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(50844-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(50844-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-375)

Revised: 11/2019

L.N.K. International, Inc.