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- 2. Loperamide
- FDA PI

Anti-Diarrheal Tablet: Package Insert / Prescribing Info



Package insert / product label

Generic name: loperamide hydrochloride

Dosage form: tablet
Drug class: Antidiarrheals

Medically reviewed by Drugs.com. Last updated on Aug 24, 2023.

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Active ingredient (in each caplet)

Loperamide HCl 2 mg

Purpose

Anti-diarrheal

Indications and Usage for Anti-Diarrheal Tablet

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.

Anti-Diarrheal Tablet Dosage and Administration

- · 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

Storage and Handling

- 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 HCI 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



Quality Plus 44-375

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

2 mg

LOPERAMIDE HYDROCHLORIDE (UNI: 77TI35393C) (LOPERAMIDE - LOPERAMIDE

UNII:6X9OC3H4II) HYDROCHLORIDE

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

Colorgreen (light)Score2 piecesShapeOVALSize10mm

Flavor Imprint Code 44;375

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-375-45	1 in 1 CARTON	05/03/2005	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50844-375-02	3 in 1 CARTON	05/03/2005	
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50844-375-95	2 in 1 CARTON	05/03/2005	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:50844-375-08	4 in 1 CARTON	05/03/2005	
4		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

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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. 832867837 manufacture(50844-375), pack(50844-375)

Establishment

Name Address ID/FEI Business Operations

LNK International, Inc. 117025878 manufacture (50844-375)

Frequently asked questions

• How long does Imodium stop diarrhea for?

More about loperamide

- Check interactions
- Compare alternatives
- · Pricing & coupons
- Reviews (91)
- Drug images
- Latest FDA alerts (3)
- · Side effects
- Dosage information
- Patient tips
- During pregnancy
- Drug class: antidiarrheals
- Breastfeeding
- En español

Patient resources

- Loperamide drug information
- Loperamide Capsules and Tablets

• Loperamide Oral Solution and Suspension

Professional resources

- Loperamide monograph
- Loperamide (FDA)
- Loperamide Oral Solution (FDA)

Other brands

Imodium, Imodium A-D, Anti-Diarrheal, Up and Up Anti-Diarrheal Solution

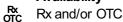
Related treatment guides

- Irritable Bowel Syndrome
- Diarrhea, Chronic
- Traveler's Diarrhea
- Diarrhea, Acute
- Lymphocytic Colitis
- Diarrhea

Medical Disclaimer

DRUG STATUS

Availability



Pregnancy & Lactation

∾ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

□ Drug history at FDA

User Reviews & Ratings

8.4 / 10

91 Reviews

Images

Loperamide Hydrochloride 2 mg (L 2)



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Access drug & treatment information, identify pills, check interactions and set up personal medication records.





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