

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Medline Industries, LP

664 Loperamide Hydrochloride

Active ingredient (in each caplet)

Loperamide HCl USP, 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 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 side panel for lot number and expiration date
- **TAMPER EVIDENT: THIS PRODUCT IS PROTECTED WITH SEALED BLISTER UNITS. DO NOT USE IF ANY ARE TORN OR BROKEN.**

Inactive ingredients

anhydrous lactose, croscarmellose sodium, crospovidone, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

Questions or comments?

Call toll free **1-800-MEDLINE (633-5463)**
Monday-Friday 9AM-5PM CST

Manufacturing Information

Packaged for:
Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA
Packaged in USA with domestic and foreign materials
www.medline.com
1-800-MEDLINE (633-5463)
REF: OTCS0801C2
V1 RG22OHM

Package Label

Directions
 Take 1 caplet after each episode of diarrhea. Do not take more than 4 caplets in 24 hours.
 If you are taking other medicines, ask your doctor or pharmacist for advice. Do not take more than 4 caplets in 24 hours.
 If you are taking other medicines, ask your doctor or pharmacist for advice. Do not take more than 4 caplets in 24 hours.

Warnings
 Allergic reactions: If you have had an allergic reaction to loperamide hydrochloride, do not take it. Taking more than the recommended dose can cause dizziness or death.
 Use can have symptoms of overdose, including: Tremors, Dizziness

Drug Facts (continued)
 Do not use if you have had your bowels blocked. Do not use if you have had your bowels blocked. Do not use if you have had your bowels blocked.
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Other information
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Questions or comments?
 Call toll free 1-800-MEDLINE (633-6363) for more information.

Drug Facts
 Active ingredient (in each caplet): Loperamide HCl USP 2 mg.
 Purpose: Anti-diarrheal.
 Use can have symptoms of overdose, including: Tremors, Dizziness

MEDLINE
Loperamide HCl Tablets USP, 2 mg
 Anti-Diarrheal
 12 Caplets*
 2 mg each

MEDLINE
 Compare to the active ingredient in Imodium® A-D
Loperamide HCl Tablets USP, 2 mg
 Anti-Diarrheal
 Controls the symptoms of diarrhea
 12 Caplets*
 *capsule-shaped tablet
 See now warnings and directions
 2 mg each

NON VARNISH
 LOT
 EXP

Lot # & Expiration Date will be imprinted at time of manufacture.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
 Medline Industries, L.P.
 1-800-MEDLINE
 84389823425

LOPERAMIDE HYDROCHLORIDE
 loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-664
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TRISTEARIN (UNII: P6OCJ2551R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	green	Score	2 pieces
Shape	CAPSULE	Size	9mm
Flavor		Imprint Code	123
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-664-57	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/01/1993	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074091	02/01/1993	

Labeler - Medline Industries, LP (025460908)**Registrant** - Medline Industries, LP (025460908)

