

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Marc Glassman, Inc.

Loperamide Hydrochloride

Drug Facts

Active ingredient (in each caplet)

Loperamide Hydrochloride 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 hydrochloride

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

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; ½ 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; ½ caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children 2-5 years (34 to 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?

Call toll-free Monday-Friday 8:30 am to 5 pm EST at **1800-406-7984**.

Distributed by:
Marc Glassman, Inc.
West 130th Street
Cleveland, OH 44130

PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton

†Compare to the active
ingredient of Imodium[®] A-D

Marc's[®]

See New Warnings
and Directions

Loperamide Hydrochloride
Tablets USP, 2 mg

Anti-
Diarrheal
Controls The Symptoms of Diarrhea

Each caplet (*capsule-shaped tablet)
contains Loperamide Hydrochloride USP, 2 mg

24 Caplets*

Loperamide Hydrochloride Tablets USP
Anti-Diarrheal

Marc's

Marc's

†Compare to the active ingredient of Imodium® A-D

See New Warnings and Directions

Loperamide Hydrochloride Tablets USP, 2 mg

Anti-Diarrheal

Controls The Symptoms of Diarrhea

are property of their respective owners. This product is not affiliated with the of Imodium® A-D.

Expiration Date:

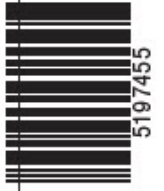
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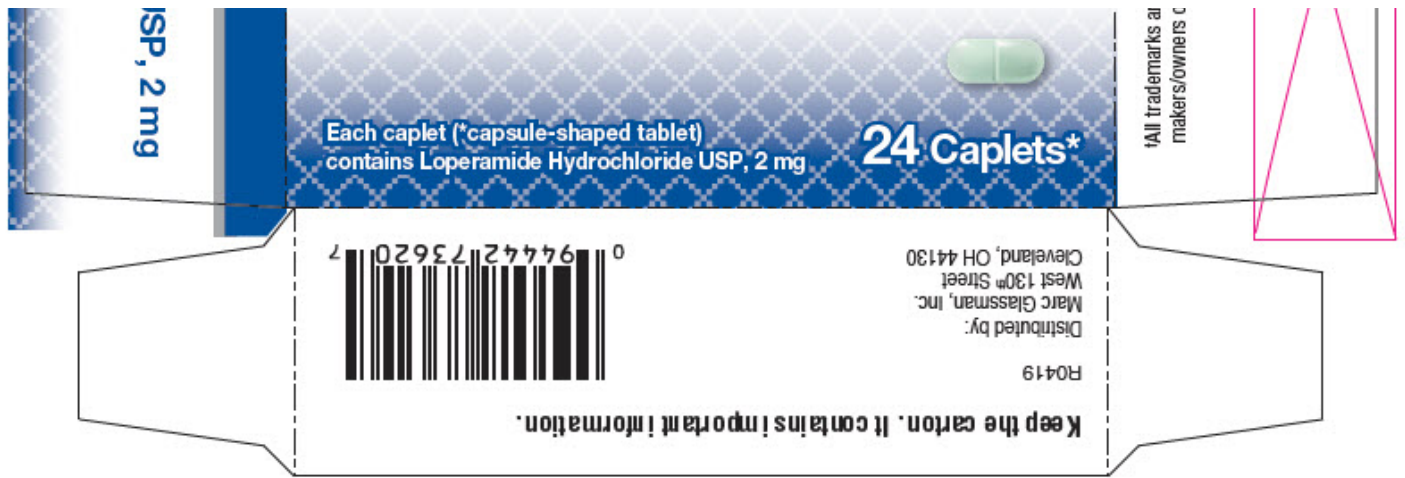
Lot No.:

Drug Facts
Active ingredient (in each caplet)
 Loperamide Hydrochloride USP, 2 mg
Purpose
 Ant-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 piperamide hydrochloride
Heart alert: Taking more than directed can cause serious heart problems or death

Drug Facts (continued)
 Do not use if you have bloody or black stool
 Ask a doctor or pharmacist before use if you have:
 ■ a history of abnormal heart rhythm
 ■ a history of liver disease
 ■ muscle in the stomach
 ■ fever
 Ask a doctor or pharmacist before use if you have:
 ■ a history of liver disease
 ■ a history of abnormal heart rhythm
 ■ a history of abnormal heart rhythm
 Taking a prescription drug Loperamide may interact with certain prescription drugs.
 When using this product, dizziness, 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 right away (1-800-222-1222).
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 side panel for lot number and expiration date
 ■ TAMPER EVIDENT: THIS PRODUCT IS PROTECTED WITH SEALED BUSTERS. DO NOT USE IF ANY ARE TORN OR BROKEN.
Inactive ingredients
 anhydrous lactose, croscarmellose sodium, croscopolamide, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hydroxypropyl methylcellulose, pregelatinized starch
Questions? Call toll-free Monday-Friday 8:30 am to 5 pm EST at 1800-406-7984.





LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-123
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPROVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-123-24	4 in 1 CARTON	05/01/2018	
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	ANDA074091	05/01/2018	

Labeler - Marc Glassman, Inc. (094487477)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(68998-123)

Revised: 1/2024

Marc Glassman, Inc.