

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Ohm Laboratories Inc.

Loperamide Hydrochloride Tablets USP, 2 mg

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 **1-800-406-7984**

Keep the carton. It contains important information.

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901

R0319

PRINCIPAL DISPLAY PANEL

NDC 51660-123-06

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

**See New Warnings
and Directions**

ohm[®]

**Loperamide Hydrochloride
Tablets USP, 2 mg**

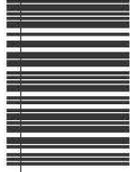
Anti-Diarrheal

Controls the symptoms of diarrhea

6 Caplets*

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

**†Ohm[®] is a registered trademark of Sun Pharmaceutical Industries, Inc. All
other trademarks are property of their respective owners.**



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Drug Facts (continued)

Do not use if you have bloody or black stool

Ask a doctor before use if you have

- fever
- 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
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- 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

Drug Facts (continued)

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 BUSTER UNITS. DO NOT USE IF ANY ARE TORN OR BROKEN.

Inactive ingredients

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

Questions? call 1-800-406-7994



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Drug Facts

Active ingredient (in each caplet)

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Purpose

Anti-diarrheal

Use

controls 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 hydrochloride

Heart alert: Taking more than directed can cause serious heart problems or death

NDC 51660-123-06

See New Warnings and Directions

ohm

Loperamide Hydrochloride Tablets USP, 2 mg Anti-Diarrheal

Controls the symptoms of diarrhea

6 Caplets*

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

†Compare To the active ingredient of **Imodium® A-D**

ohm

Loperamide Hydrochloride Tablets USP, 2 mg Anti-Diarrheal

Controls the symptoms of diarrhea

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

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Expiration Date:

NON VARNISH

Lot No.:

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Ohm Laboratories Inc.
New Brunswick, NJ 08901

R0319



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51660-123
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STARCH, 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:51660-123-06	1 in 1 CARTON	02/01/1993	

1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:51660-123-12	2 in 1 CARTON	02/01/1993	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:51660-123-24	4 in 1 CARTON	02/01/1993	
3		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	02/01/1993	

Labeler - Ohm Laboratories Inc. (184769029)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(51660-123)

Revised: 1/2024

Ohm Laboratories Inc.