LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Chain Drug Marketing Association 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 useif 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 aretaking a prescription drug. Loperamide may interact with certain prescription drugs.

When using this producttiredness, 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 C.D.M.A., Inc.©
43157 W. Nine Mile
Novi, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 2 mg Caplet Blister Pack Carton

QUALITY ®
CHOICE

NDC 63868-338-12

*Compare to
Active Ingredient in
IMODIUM ®A-D

See New Warnings and Directions

Loperamide Hydrochloride
Tablets USP, 2 mg

Anti-Diarrheal

Controls The Symptoms of Diarrhea

12 Caplets*

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

NDC 63868-338-12

QUALITY CHOICE

*Compare to Active Ingredient In IMODIUM® A-D

See New Warnings and Directions

Loperamide Hydrochloride Tablets USP, 2 mg

Anti-Diarrheal

Controls The Symptoms of Diarrhea

12 Caplets* Each caplet (Caplet = capsule-shaped tablet)

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Imodium® A-D.

Lot No.: Expiration Date:

NON VARNISH

5197459

QUALITY CHOICE

Loperamide Hydrochloride Tablets USP, 2 mg

Anti-Diarrheal

5197459

Drug Facts

Active ingredient (in each caplet) — **Purpose**

Loperamide Hydrochloride USP, 2 mg ..... 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

Drug Facts (continued)

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

Drug Facts (continued)

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

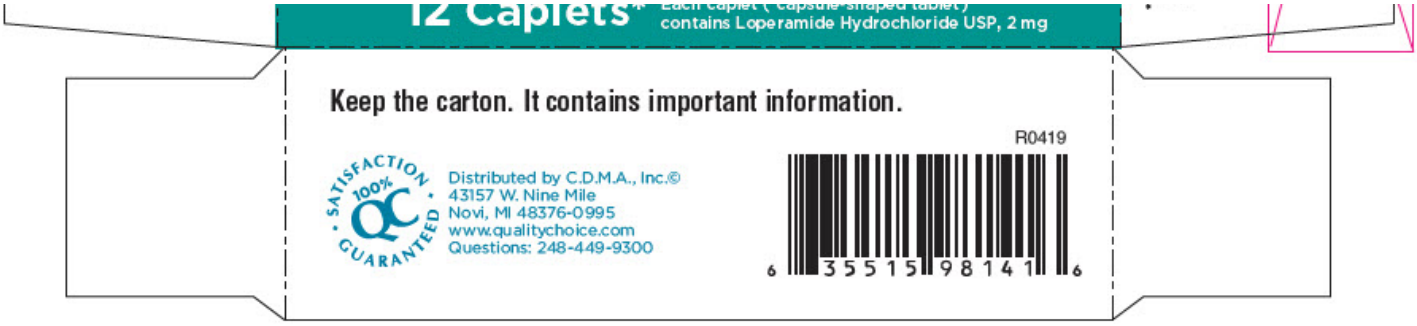
- store between 20° – 25°C (68° – 77°F)
- see side panel for lot number and expiration date
- **TAMPER EVIDENT THIS PRODUCT IS PROTECTED WITH SEALED BLISTER UNITS. DO NOT USE IF ANY ARE TORN OR BROKEN.**

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 1-800-406-7984.



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-338
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (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:63868-	24 in 1 BLISTER PACK; Type 0: Not a Combination	02/01/1993	

1	338-24	Product	02/01/1993	
2	NDC:63868-338-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/1993	
3	NDC:63868-338-12	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 - Chain Drug Marketing Association Inc. (011920774)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		051565745	manufacture(63868-338)

Revised: 1/2024 Chain Drug Marketing Association Inc.