LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Medline Industries, Inc.

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 HCI
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

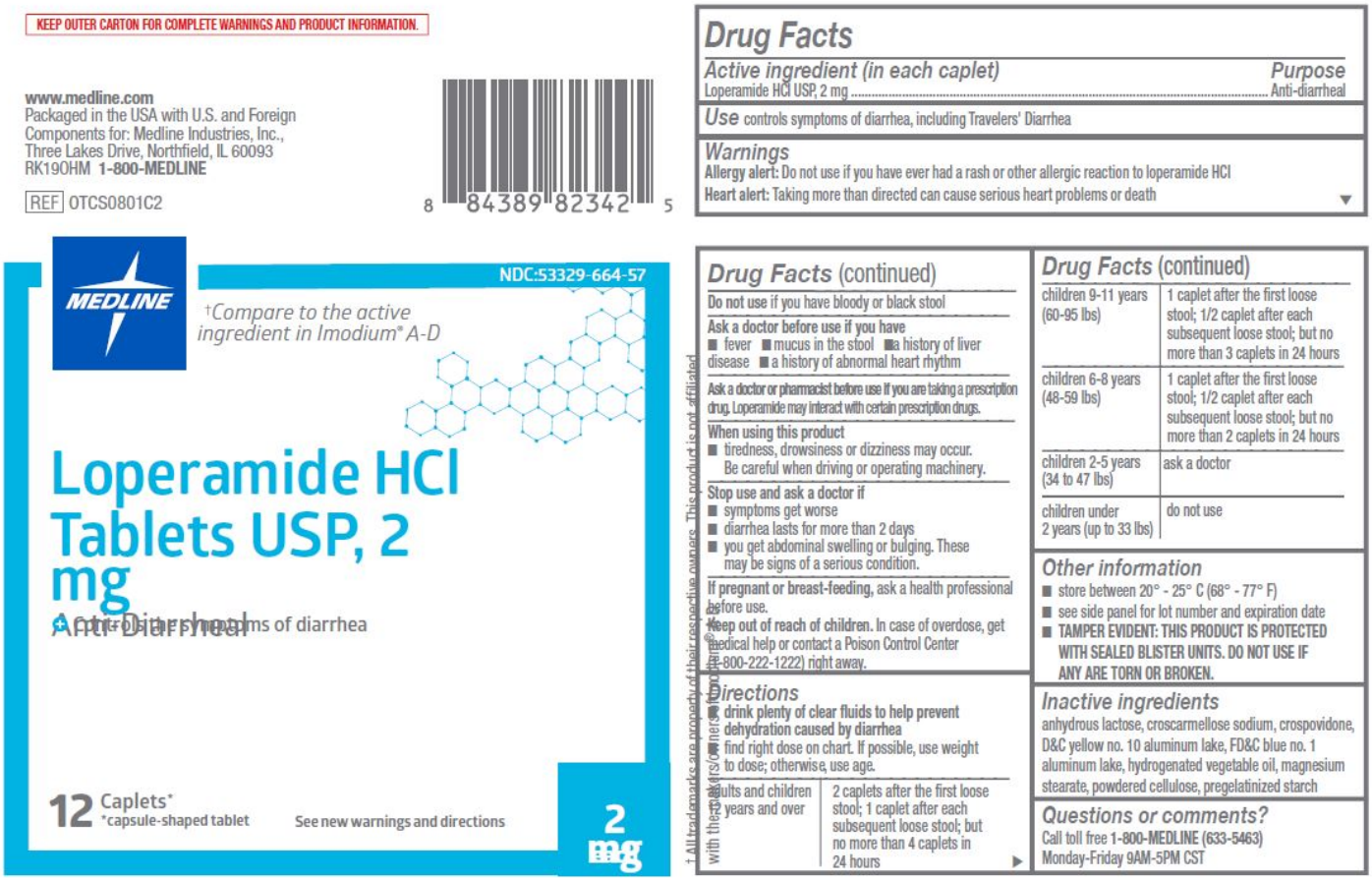
anhydrous lactose, croscarmellose sodium, crospovidone, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

Questions or comments?

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

www.medline.com
Packaged in the USA with U.S. and Foreign
Components for: Medline Industries, Inc.,
Three Lakes Drive, Northfield, IL 60093
RK19OHM **1-800-MEDLINE**

Package Labels



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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (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, Inc. (025460908)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(53329-664)

Revised: 12/2019 Medline Industries, Inc.