LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet Ameris ource Bergen

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

Loperamide HCI 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

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

Ask a doctor or pharmacist before use if you are

Taking antibiotics

When using this product

• tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

Stop use and ask a doctor if

- diarrhea lasts for more than 2 days
- symptoms get worse
- 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 under 6 years (up to 47 lbs)	ask a doctor

OTHER INFORMATION

- store between $20^{\circ} 25^{\circ}$ C $(68^{\circ} 77^{\circ}$ F)
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.

INACTIVE INGREDIENTS

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

QUESTIONS?

Call 1800-406-7984

PRINCIPAL DISPLAY PANEL

GOOD NEIGHBOR PHARMACY®

NDC 46122-0169-08

*Compare to Imodium*A-D active ingredient

Loperamide HCl Tablets USP, 2 mg

Anti-Diarrheal

Controls the Symptoms of Diarrhea

72 caplets

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

Distributed By: AmerisourceBergen

5098330/R0912



INSIDE TOP LABEL BASE LABEL

Drug Facts (continued)	Drug Facts (continued)		
Ask a doctor or pharmacist before use if you are taking antibiotics	Keep out of reach of children. In case of overdose, get medic		
When using this product	or contact a Poison Control Center right away (1-800-222-1222).		
 tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery. 	Directions m drink plenty of clear fluids to help prevent dehydration		
Stop use and ask a doctor if diarrhea lasts for more than 2 days symptoms get worse	caused by diarrhea find right dose on chart. If possible, use weight to dose; otherwise, use age.		
you get abdominal swelling or bulging. These may be signs of a serious condition.	adults and children 2 caplets after the first loose stool 12 years and over 1 caplet after each		
If pregnant or breast-feeding, ask a health professional before use.	subsequent loose stool; but no more than 4 caplets in 24 hours		



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-169	
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			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)				
CROSPO VIDO NE (UNII: 6840 1960 MK)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
TRISTEARIN (UNII: P6OCJ2551R)				
MAGNESIUM STEARATE (UNII: 70097M6130)				
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK)				

Product Characteristics			
Color	green	Score	2 pieces
Shape	CAPSULE	Size	9 mm

Flavor		Imprint Code		123
Contains				
Packaging				
# Item Code	Package Description	Marketin	g Start Date	Marketing End Date
NDC:46122-169-08	72 in 1 BOTTLE			
Marketing Information				
LITURE TIC CHILLS THE		l. C'	Marketing Start D	ate Marketing End Date
	Application Number or Moneg			
Marketing Category	Application Number or Monog ANDA074091	raph Citation	02/01/1993	ate Marketing Life Date

Labeler - Amerisource Bergen (007914906)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ohm Laboratories Inc.		051565745	manufacture(46122-169)	

Revised: 10/2012 Amerisource Bergen