

LOPERAMIDE HYDROCHLORIDE - loperamide hydrochloride tablet

Physicians Total Care, Inc.

Drug Facts

ACTIVE INGREDIENT (IN EACH CAPLET)

Loperamide HCl USP, 2 mg

PURPOSE

Anti-diarrheal

USE(S)

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 HCl

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.

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° – 25° C (68° – 77° F)
- see side panel for lot number and expiration date
- **TAMPER EVIDENT: THIS PRODUCT 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, FD&C blue no.1, hydrogenated vegetable oil, magnesium stearate, powdered cellulose, pregelatinized starch

QUESTIONS?

call **1800-406-7984**

Keep the carton. It contains important information.

Distributed by:

Ohm Laboratories Inc.

1385 Livingston Avenue

North Brunswick, NJ 08902

PRINCIPAL DISPLAY PANEL

NDC 54868-6312-0

Loperamide HCl Tablets, USP 2 mg

Anti-Diarrheal

12 CAPLETS[†]

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

Controls The Symptoms of Diarrhea

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



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:54868-6312(NDC:51660-123)	
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: M28OL1HH48)				
CROSPVIDONE (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, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
TRISTEARIN (UNII: P6OCJ2551R)				
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)				
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:54868-6312-0	12 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074091	09/24/2011	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 4/2012

Physicians Total Care, Inc.