LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet Proficient Rx LP

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 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	2 caplets after the first loose stool;
12 years and over	1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years	1 caplet after the first loose stool;
(60-95 lbs)	½ caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years	1 caplet after the first loose stool;
(48-59 lbs)	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.

New Brunswick, NJ 08901

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL

NDC 63187-462-12

Loperamide HCI Tablets, USP 2 mg

Anti-Diarrheal

12 CAPLETS[†]

Each caplet(†capsule-shaped tablet) contains Loperamide HCl, USP 2 mg Controls The Symptoms of Diarrhea

Imodium® is a registered trademark of Johnson & Johnson.





NDC 63187-462-12

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Loperamide HCI 2mg #12 Tablets Lot #:00000 NDC 63187-462-12

Loperamide HCI 2mg

SN# MASTER Exp:00/00/00

#12 Tablets Lot #:00000 NDC 63187-462-12 SN# MASTER Exp:00/00/00

Loperamide HCl 2mg #12 Tablets Lot #:00000 NDC 63187-462-12

SN# MASTER Exp:00/00/00

GTIN: 00363187462123 SN# MASTER Exp. 00/00/00 Lot #:00000

Loperamide HCI 2mg

#12

Tablets

Each caplet contains: Loperamide Hydrochloride USP, 2 mg Anti-diarrheal

See Box

Product ID: RL046212

Dist. By: Ohm Laboratories Inc. New Brunswick, NJ 08901

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63187-462(NDC:51660-123)

Route of Administration

ORAL

^{*}Compare to the active ingredient of Imodium® A-D

^{*}This product is not manufactured or distributed by McNeil-PPC, distributor of Imodium® A-D.

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)		
CROSPOVIDONE (120 .MU.M) (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, CORN (UNII: O8232NY3SJ)		
GLYCERYL TRISTEARATE (UNII: P6OCJ2551R)		
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)		

Product Characteristics			
Color	green	Score	2 pieces
Shape	CAPSULE	Size	9mm
Flavor		Imprint Code	123
Contains			

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
		DC:63187- 62-12	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	03/27/2014	

Marketing Information			
Marketing Application Number or Monograp Category Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA074091	02/01/1993	

Labeler - Proficient Rx LP (079196022)

Establishment			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-462), RELABEL(63187-462)

Revised: 5/2022 Proficient Rx LP