

ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled
CVS Pharmacy, Inc.

Drug Facts

Active ingredient (in each capsule)

Loperamide HCl 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 HCl

Heart alert: Taking more than directed can cause serious heart problems or death

Do not use

- if you have bloody or black stool
- in children under 12 years of age

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.

Directions

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea.**
- **not for use in children under 12 years of age**
- adults and children 12 years and over: 2 capsules after the first loose stool; 1 capsule after each subsequent loose stool; but no more than 4 capsules in 24 hours

Other information

- store at 20°-25°C (68°-77°F). Protect from light.
- avoid excessive heat above 40°C (104°F)
- do not use if carton or blister unit is open or torn
- see side panel for lot number and expiration date

Inactive ingredients

butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water

Questions or comments?

call toll free **1-888-235-2466** (Mon - Fri 9AM - 5PM EST)

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

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER-EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com[®] 1-800-SHOP CVS

V-34338

L000562

Lot #

Expiration Date

R02/22

Principal Display Panel

CVS Health[™]

Compare to the active ingredient in Imodium[®] A-D[†]

Anti-Diarrheal

LOPERAMIDE HCl SOFT GELATIN

CAPSULES, 2 mg

Controls the symptoms of diarrhea

Suitable for adults and

children 12 years and over

Actual Size

Liquid-Filled Capsules*

24 SOFTGELS*

***Each liquid-filled capsule**

contains 2 mg loperamide HCl





ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-061
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
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)				
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	LP2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-061-12	2 in 1 CARTON	12/04/2018	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021855	12/04/2018	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Bionpharma Inc. (079637826)

Establishment			
Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(69842-061)