

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

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***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 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels 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**

†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**

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**One CVS Drive, Woonsocket, RI 02895**

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**Rev # 12/18**

**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

24 Softgels\*

\*Each liquid-filled capsule contains 2 mg loperamide HCl

# Anti-Diarrheal

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Controls the symptoms of diarrhea

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# Anti-Diarrheal

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Actual Size Liquid-Filled Capsules\*

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\*Each liquid-filled capsule contains 2 mg loperamide HCl

#690041

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

COATING FREE AREA

Lot #  
Expiration Date  
File # 12/18

L0000100

**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 or if you have had a heart problem or death in children under 12 years of age.  
 Ask a doctor before use if you have a fever, mucus in the stool, or a history of liver disease.  
 Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.

**Directions**  
 Drink plenty of clear fluids to help prevent dehydration caused by diarrhea.  
 Adults and children 12 years and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours.  
 Children under 12 years of age: Do not use.

**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**  
 polyoxy 40 hydrogenated castor oil, purified water, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, and others.

**Questions or comments?** call toll free 1-888-235-2466

COATING FREE AREA

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## 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: 059QF0K00R)	

### Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	10 mm
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)

Revised: 6/2019

CVS Pharmacy, Inc.