

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled  
CARDINAL HEALTH**

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***Loperamide HCl Capsules - Leader***

***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**

**CardinalHealth™**

**DISTRIBUTED BY CARDINAL HEALTH**

**DUBLIN, OHIO 43017**

**www.myleader.com 1-800-200-6313**

**Essential to Care™ since 1979**

**All LEADER™ Brand Products Have A 100% Money Back Guarantee**

**Return to place of purchase if not satisfied.**

**†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademark Imodium® A-D.**

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**Manufactured for:**

**BIONPHARMA  
600 Alexander Road,  
Princeton, NJ 08540**

**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.**

**L0000566**

**Lot#**

**Expiration Date**

**R03/22**

**Principal Display Panel**

LEADER <sup>TM</sup>

NDC 70000-0461-1

Anti-Diarrheal

Loperamide Hydrochloride 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

Actual Size

COMPARE TO

IMODIUM <sup>®</sup> A-D

active ingredient †

100 % Money Back Guarantee



**ANTI-DIARRHEAL**  
 loperamide hydrochloride capsules, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0461
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	LP2
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0461-1	2 in 1 CARTON	01/21/2019	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA021855	01/21/2019	

**Labeler** - CARDINAL HEALTH (063997360)

**Registrant** - Bionpharma Inc. (079637826)

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## Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(70000-0461)

Revised: 5/2022

CARDINAL HEALTH