

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled**  
**Northeast Pharma**

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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 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)

Distributed by:

**NORTHEAST PHARMA**

South Burlington, VT 05403

[www.heartlandpharmaco.com](http://www.heartlandpharmaco.com)

1-800-383-0648

L0000440

Rev # 11/19

†This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark 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.**

### Principal Display Panel



NDC 80136-851-42

Heartland Pharma Co.

ANTI-DIARRHEAL

Loperamide HCl Capsules, 2 mg  
Controls the Symptoms  
of Diarrhea

Suitable for adults and  
children 12 years and over

actual size

Compare to active ingredient in Imodium® A-D†

24 Softgels\*

\*soft gelatin liquid filled capsules

each softgel contains 2 mg loperamide HCl

carton

## ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80136-851
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<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:80136-851-42	2 in 1 CARTON	05/21/2021	
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	05/21/2021	

**Labeler** - Northeast Pharma (081232935)

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Patheon Softgels Inc.		002193829	manufacture(80136-851)

Revised: 12/2022

Northeast Pharma