

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

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

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

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: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

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