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

Drug Facts

Active ingredient (in each capsule)

Loperamide HCI 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

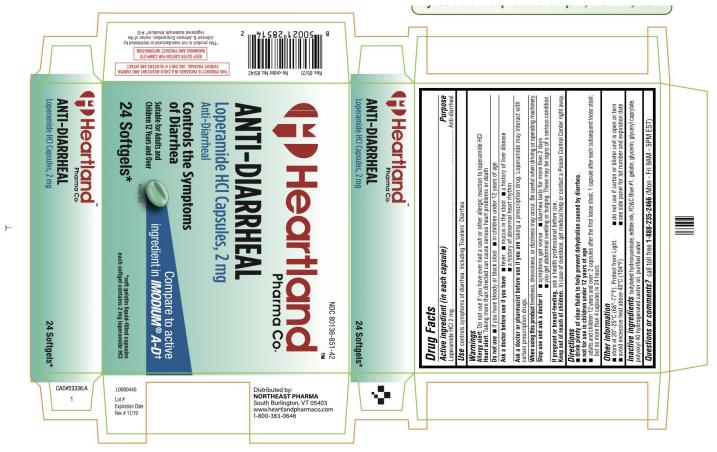
†This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Imodium $^{\mbox{\tiny B}}$ A-D.

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

loperamide hydr	ochionae							
Product Info	rmation							
Product Type		HUMAN OT	C DRUG	Item Cod	e (Sourc	e)	NDC:801	36-851
Route of Admir	nistration	ORAL						
Active Ingred	lient/Acti	ve Moiety						
	In	gredient Nar	ne		Ba	sis of St	trength	Strengt
LOPERAMIDE HYI UNII:6X9OC3H4II)	PERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - LOPERAMIDE				E	2 mg		
Inactive Ingr	edients							
		Ingree	dient Name				S	trength
BUTYLATED HYD	ROXYANISO	LE (UNII: REK49	60K2U)					
FD&C BLUE NO.	1 (UNII: H3R4	47K3TBD)						
GELATIN (UNII: 2G	86QN327L)							
GLYCERYL CAPR	(LATE (UNII:	TM2TZ D4G4A)						
GLYCERYL CAPRY POLYOXYL 40 HY	(LATE (UNII: DROGENAT	TM2TZ D4G4A)	L (UNII: 7YC6860	GQ8F)				
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GLYCERYL CAPRY POLYOXYL 40 HY	(LATE (UNII: DROGENAT	TM2TZ D4G4A)	L (UNII: 7YC6860	GQ8F)				
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Labeler - Northeast Pharma (081232935)

Registrant - Bionpharma Inc. (079637826)

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

Revised: 12/2022

Northeast Pharma