ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled PUBLIX SUPER MARKETS INC

Publix-Loperamide HCI Capsules 2mg

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**(Mon - Fri 9AM - 5PM EST)

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.

*This product is not manufactured or distrbuted by the owners of Imodium ®A-D

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC., 3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811 1-888-267-3037 publix.com

PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

Publix

L0000869

R0524

Lot #

Expiration Date

Carton

NDC 56062-680-12

Anti-Diarrheal

LOPERAMIDE HCI CAPSULES, 2 mg

- Controls the symptoms of diarrhea
- Suitable for adults and children

12 years and over

ACTUAL SIZE

24 Softgels*

*Soft gelatin liquid-filled capsules; each softgel contains 2 mg loperamide HCl.

Compare to the active ingredient in imodium® A-D†





ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:56062-680

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)

Basis of Strength

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: TM2TZ D4G4A)		
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				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:56062- 680-12	2 in 1 CARTON	10/07/2024		
:	L	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	10/07/2024	

Labeler - PUBLIX SUPER MARKETS INC (006922009)

Registrant - Bionpharma Inc. (079637826)

Establishment				
Name	Address	ID/FEI	Business Operations	
Patheon Softgels Inc.		002193829	manufacture(56062-680)	

Revised: 10/2024 PUBLIX SUPER MARKETS INC