

ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled
KROGER COMPANY

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 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?

1-800-632-6900

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.

****IMODIUM® IS A REGISTERED TRADEMARK OF JOHNSON & JOHNSON, NEW BRUNSWICK, NJ 08933. JOHNSON & JOHNSON IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.**

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

QUALITY GUARANTEE

www.kroger.com

Rev # 01/19

Principal Display Panel

COMPARE TO the active ingredient of IMODIUM® A-D

****See bottom panel**

Kroger®

Anti-Diarrheal

Loperamide HCl Soft Gelatin Capsules, 2 mg

CONTROLS THE SYMPTOMS OF DIARRHEA

Suitable for Adults and Children 12 Years and Over

12 SOFTGELS*

*Each Liquid-Filled Capsule Contains 2 mg Loperamide HCl



ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-159
Route of Administration	ORAL		

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: 059QF0K00R)	

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:30 142-159-08	1 in 1 CARTON	03/01/2019	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30 142-159-12	2 in 1 CARTON	03/01/2019	
2		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	03/01/2019	

Labeler - KROGER COMPANY (006999528)**Registrant** - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(30142-159)

Revised: 8/2019

KROGER COMPANY