

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled
AMERISOURCE BERGEN**

GNP Loperamide HCl Capules

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**

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Distributed By
AmerisourceBergen

1 West First Ave

Cornshohocken, PA 19428

Questions or Concerns?

www.mygnp.com

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

GOOD NEIGHBOR PHARMACY[®]

Compare to Imodium[®] A-D active ingredient[†]

NDC 46122-581-62

Anti-Diarrheal

loperamide HCl soft gelatin capsules, 2 mg

Controls the Symptoms of Diarrhea

suitable for adults and children 12 years and over

24 softgels*

***each liquid-filled capsule contains 2 mg loperamide HCl**



Drug Facts

Active ingredient (in each capsule) Loperamide HCl 2 mg, Anti-diarrheal

Use Controls symptoms of diarrhea, including Traveler's Diarrhea

Warnings 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, if children under 12 years of age, if you have fever, if you have mucus in the stool, if you have a history of liver disease, if you have 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: heaves, 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 bloating. 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). See side panel for lot number and expiration date. Do not use if carton or blister unit is open or torn.

Inactive ingredients butylated hydroxytoluene, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyvinyl alcohol, purified water.

Questions or comments? call toll free 1-888-235-2466



Anti-Diarrheal
loperamide HCl soft gelatin capsules, 2 mg



Compare to Imodium® A-D active ingredient*

NDC 46122-581-62



Anti-Diarrheal
loperamide HCl soft gelatin capsules, 2 mg

Controls the Symptoms of Diarrhea
suitable for adults and children 12 years and over

24 softgels* | each liquid-filled capsule contains 2 mg loperamide HCl



Anti-Diarrheal
loperamide HCl soft gelatin capsules, 2 mg

Distributed By:
Amgen
1 West Park Ave
Conshohocken, PA 19428
Questions or Concerns?
www.amgen.com

L2009038
Lot #
Expiration Date
Rev # 04/21

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THIS PRODUCT CONTAINS PLACEBO-CONTAINING AND TARTARIC ACID. PLEASE READ THE ENTIRE LABEL FOR FULL DIRECTIONS AND PRECAUTIONS.

CA023303-A
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ANTI-DIARRHEAL
loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-581
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: 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:46122-581-62	2 in 1 CARTON	02/15/2019	
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	02/15/2019	

Labeler - AMERISOURCE BERGEN (007914906)**Registrant** - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(46122-581)

Revised: 3/2022

AMERISOURCE BERGEN