

LOPERAMIDE HCL- loperamide hydrochloride capsule, liquid filled
Chain Drug Consortium, LLC

Premier Value Loperamide HCl Capsules

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

Ask a doctor or pharmacist before use if you are

taking antibiotics.

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 of age 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

*COMPARE TO THE ACTIVE INGREDIENT IN IMODIUM® A-D

Anti-Diarrheal

Loperamide HCl

Soft Gelatin Capsules, 2 mg

Controls the Symptoms of Diarrhea

Suitable for adults and children 12 years and over

Softgels**

**each liquid-filled capsule

contains 2 mg loperamide HCl

*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, Distributor of 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.

Distributed By: Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

Product Labeling

This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

<p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	<p>signs of a serious condition. ■ you get abdominal swelling or bulging. These may be ■ diarrhea lasts for more than 2 days ■ symptoms get worse Stop use and ask a doctor if</p>
<p>Inactive ingredients butylated hydroxyanisole, edible ink, FD&C blue #1, gelatin, glycerin, glyceryl caprylate, polyoxy 40 hydrogenated castor oil, purified water</p>	<p>When using this product tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.</p>
<p>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</p>	<p>Ask a doctor or pharmacist before use if you are taking antibiotics. Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease ■ in children under 12 years of age ■ if you have bloody or black stool</p>
<p>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 of age 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</p>	<p>Do not use ■ if you have bloody or black stool ■ if you have had a rash or other allergic reaction to loperamide HCl. Heart alert: Taking more than directed can cause serious heart problems or death.</p>
<p>Drug Facts (continued) 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.</p>	<p>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. Travelers' Diarrhea.</p>
<p>Use Controls symptoms of diarrhea, including Travelers' Diarrhea.</p>	<p>Active ingredient (in each capsule) Loperamide HCl 2 mg.....Anti-diarrheal</p>
<p>Purpose</p>	<p>Drug Facts</p>



Anti-Diarrheal

Loperamide HCl
Soft Gelatin Capsules, 2 mg





*COMPARE TO THE ACTIVE INGREDIENT
IN IMODIUM® A-D

Anti-Diarrheal

Loperamide HCl

TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.
 WARNINGS AND PRODUCT INFORMATION.

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



THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND
 KEEP OUTER CARTON FOR COMPLETE

Lot / Exp.:
 Product of:



REV # 9/16
 PLD-D45J
 FC003353

If for any reason you are not satisfied with
 this product, please return it to the store
 where purchased for a full refund.

Distributed By: Pharmacy Value Alliance, LLC
 407 East Lancaster Avenue,
 Wayne, PA 19087



PREMIER VALUE Anti-Diarrheal

LOPERAMIDE HCL

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-193
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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	9mm
Flavor		Imprint Code	p13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-193-12	2 in 1 BOX	12/04/2012	
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	12/04/2012	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 3/2017

Chain Drug Consortium, LLC