ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled The Kroger Co.

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

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?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredient of IMODIUM® A-D *See side panel

Anti-Diarrheal

Loperamide HCI

Soft Gelatin Capsules 2 mg

CONTROLS THE SYMPTOMS OF DIARRHEA

Suitable for Adults and Children 12 Years and Over

SOFTGELS**

*Imodium® A-D is a registered trademark of McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA 19034, McNeil Consumer & Specialty Pharmaceuticals is not affiliated with The Kroger Co. or this product

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

^{**}each Liquid-Filled Capsule Contains 2 mg Loperamide HCI

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202 www.kroger.com

Product Label



ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-520
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 MONOCAPRYLATE (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	P13
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:30142-520- 24	24 in 1 CARTON	12/31/2016	05/30/2025		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:30142-520- 72	72 in 1 CARTON	12/31/2016	05/30/2025		
2		1 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	12/31/2016	05/30/2025

Labeler - The Kroger Co. (006999528)

Revised: 11/2022 The Kroger Co.