ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled CVS Pharmacy

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?

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 HCI SOFT GELATIN CAPSULES, 2 MG

Controls the symptoms of diarrhea

Suitable for adults and children 12 years and over

SOFTGELS*

Liquid-Filles Softgels*

*Each liquid-filled capsule contains 2 mg loperamide hydrochloride

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: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

www.cvs.com

Product of U.S.A.

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

Product Label

■ diarrhea lasts for more than 2 days ■ symptoms get worse

Stop use and ask a doctor if

machinery.

dizziness may occur. Be careful when driving or operating When using this product tiredness, drowsiness, or

taking antibiotics.

Ask a doctor or pharmacist before use if you are

- a history of liver disease
- fever mucus in the stool
- Ask a doctor before use if you have
 - in children under 12 years of age
 - if you have bloody or black stool Do not use

neart problems or death.

Heart alert: Taking more than directed can cause serious other allergic reaction to loperamide HCI.

Allergy alert: Do not use if you have ever had a rash or SBUIUJEM

> Travelers' Diarrhea. **USE** Controls symptoms of diarrhea, including

Isedmaib-itnA..

Loperamide HCl 2 mg.

Purpose

(əjnsdeo yoeə ui) Active ingredient

Drug Facts

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments?

polyoxyl 40 hydrogenated castor oil, purified water edible ink, FD&C blue #1, gelatin, glycerin, glyceryl caprylate, Inactive ingredients butylated hydroxyanisole,

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 - Other information

loose stool; but no more than 4 softgels in 24 hours after the first loose stool; 1 softgel after each subsequent

- adults and children 12 years of age and over: 2 softgels
 - not for use in children under 12 years of age caused by diarrhea
- quink plenty of clear fluids to help prevent dehydration DILGCTIONS

medical help or contact a Poison Control Center right away. Keep out of reach of children. In case of overdose, get It pregnant or breast-feeding, ask a health professional

signs of a serious condition.

■ you get abdominal swelling or bulging. These may be

nund racts (continued)

CVSHealth.

Anti-Diarrheal

LOPERAMIDE HCI SOFT GELATIN CAPSULES, 2 mg

Controls the symptoms of diarrhea

48 SOFTGELS*

*Each liquid-filled capsule contains 2 mg loperamide HCl



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

NDC 59779-520-48

Anti-Diarrheal

LOPERAMIDE HCI SOFT GELATIN CAPSULES, 2 mg

Controls the symptoms of diarrhea

Suitable for adults and children 12 years and over



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V-14921



REV # 9/16 PLD-E45J FC002570



CVS HEALTH Anti-Diarrheal

ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

P	ro	duc	t Inf	for	ma	tion
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HUMAN OTC DRUG NDC:59779-520 Product Type Item Code (Source)

ORAL **Route of Administration**

Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDRO CHLO UNII:6 X9 O C 3 H4 II)	RIDE (UNII: 77TI35393C) (LOPERAMIDE -	LOPERAMIDE HYDROCHLORIDE	2 mg

Inactive Ingredients			
Ingredient Name	Strength		
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCERYL MONO CAPRYLATE (UNII: TM2TZD4G4A)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	10 mm	
Flavor		Imprint Code	P13	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59779-520-48	4 in 1 CARTON	07/08/2010		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:59779-520-24	2 in 1 CARTON	07/08/2010		
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:59779-520-36	3 in 1 CARTON	07/08/2010		
3		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	07/08/2010			

Labeler - CVS Pharmacy (062312574)

Revised: 10/2019 CVS Pharmacy