

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled
Care One (American Sales Company)**

Loperamide HCl 2 mg

Drug Facts

Active Ingredient (in each capsule)

Loperamide HCl 2 mg

Purpose

Anti- diarrheal

Use

controls symptoms of diarrhea, including Traveler's 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 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 and 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

2 mg Loperamide HCl

CONTROL 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 FOODHOLD U.S.A., LLC

LANDOVER, MD 20785 • 1-877-846-9949

Product Label

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

CAREone™

ANTI-DIARRRHEAL

2 mg Loperamide HCl

CAREone™

NDC 41520-520-12

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

ANTI-DIARRRHEAL

2 mg Loperamide HCl

Drug Facts

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

Purpose

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.

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.

Directions

■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea
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Inactive ingredients

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

Questions or comments? Call

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

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CONTROL SYMPTOMS OF DIARRHEA
SUITABLE FOR ADULTS AND CHILDREN
12 YEARS AND OVER



Actual Size



12 SOFTGELS**

****each liquid- filled capsule
contains 2 mg Loperamide HCl.**

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

Lot No.:
Exp. Date:

DISTRIBUTED BY FOODHOLD U.S.A., LLC
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REV # 9/16
PLD-C45J FC003763



CAREONE Anti-Diarrheal

ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-520
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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOCAPRYLATE (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	P13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-520-12	1 in 1 CARTON	08/05/2010	
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	08/05/2010	

Labeler - Care One (American Sales Company) (809183973)

Registrant - P & L Development, LLC (800014821)

Revised: 4/2017

Care One (American Sales Company)