

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

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**Loperamide HCl 2 mg D**

**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.

# ANTI-DIARRRHEAL

2 mg Loperamide HCl



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 ■ 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  
■ 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, 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:

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Quality guaranteed or your money back.  
REV # 9/16  
PLD-C45J FC003763



**CAREONE Anti-Diarrheal**

## ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-520
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOCAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	P13
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-520-12	1 in 1 CARTON	08/05/2010	05/30/2025
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	05/30/2025

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

**Registrant** - P & L Development, LLC (079765031)

Revised: 11/2022

Care One (American Sales Company)