

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled  
QUALITY CHOICE (Chain Drug Marketing Association)**

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**Drug Facts**

**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 1-248-449-9300 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

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

#### **Anti-Diarrheal**

Controls The Symptoms Of Diarrhea

Loperamide HCl, 2 mg

Suitable For Adults And Children 12 Years And Over

\*Each Liquid-Filled Capsule Contains 2 mg Loperamide HCl

Softgels\*

Distributed by C.D.M.A., Inc.®

43157 W. Nine Mile

Novi, MI 48376-0995

[www.qualitychoice.com](http://www.qualitychoice.com)

Questions: 248-449-9300

**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.**

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

#### **Product Label**

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

<p><b>Questions or comments?</b> Call 1-248-449-9300 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  <b>Stop use and ask a doctor if</b></p>
<p><b>Inactive ingredients</b> butylated hydroxyanisole, edible ink, FD&amp;C blue #1, gelatin, glycerin, glyceryl caprylate, polyoxy 40 hydrogenated castor oil, purified water</p>	<p><b>When using this product</b> tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.</p>
<p><b>Other information</b>                  ■ 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><b>Ask a doctor or pharmacist before use if you are taking</b> antibiotics.  <b>Ask a doctor before use if you have</b> ■ fever ■ mucus in the stool ■ a history of liver disease</p>
<p><b>Directions</b>                  ■ 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><b>Do not use</b>                  ■ if you have bloody or black stool                  ■ in children under 12 years of age  <b>Heart alert:</b> Taking more than directed can cause serious heart problems or death.  <b>Allergy alert:</b> Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.</p>
<p><b>Drug Facts (continued)</b>                  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><b>Warnings</b>                  ■ if you have ever had a rash or other allergic reaction to loperamide HCl.  <b>Heart alert:</b> Taking more than directed can cause serious heart problems or death.                  ■ if you have bloody or black stool                  ■ in children under 12 years of age  <b>Ask a doctor before use if you have</b> ■ fever ■ mucus in the stool ■ a history of liver disease  <b>Ask a doctor or pharmacist before use if you are taking</b> antibiotics.  <b>When using this product</b> tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.  <b>Stop use and ask a doctor if</b>                  ■ symptoms get worse                  ■ diarrhea lasts for more than 2 days                  ■ you get abdominal swelling or bulging. These may be signs of a serious condition.</p>
<p><b>Use</b> Controls symptoms of diarrhea, including Travelers' Diarrhea.</p>	<p><b>Active ingredient (in each capsule)</b> Loperamide HCl 2 mg.....Anti-diarrheal</p>
<p><b>Purpose</b></p>	<p><b>Use</b> Controls symptoms of diarrhea, including Travelers' Diarrhea.</p>



# Anti-Diarrheal

**Controls Symptoms Of Diarrhea**



NDC 63868-748-12

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

# Anti-Diarrheal

**Controls Symptoms Of Diarrhea**

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

# Loperamide HCl, 2 mg

Suitable For Adults And Children  
12 Years And Over

\*Each Liquid-Filled Capsule  
Contains 2 mg Loperamide HCl



**12** Softgels\*

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

Lot No.:  
Exp. Date:



Distributed by C.D.M.A., Inc.©  
43157 W. Nine Mile  
Novi, MI 48375  
www.qualitychoice.com  
Questions: 248-449-9300

REV # 9/16 PLD-E45J FC003593



QUALITY CHOICE Anti-Diarrheal

## ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-748
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: TM2TZD4G4A)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0K00R)	

### 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:63868-748-12	1 in 1 CARTON	05/31/2013	
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	05/31/2013	

**Labeler** - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2019

QUALITY CHOICE (Chain Drug Marketing Association)