

ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled
CHAIN DRUG MARKETING ASSOCIATION INC.

Loperamide HCl Capsules - Quality Choice

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
- a history of abnormal heart rhythm

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Loperamide may interact with certain prescription drugs.

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 and over: 2 capsules after the first loose stool; 1 capsule after each subsequent loose stool; but no more than 4 capsules 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 toll free **1-888-235-2466**

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.

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Imodium ® A-D

L0000568

Lot #

Expiration Date

R0322

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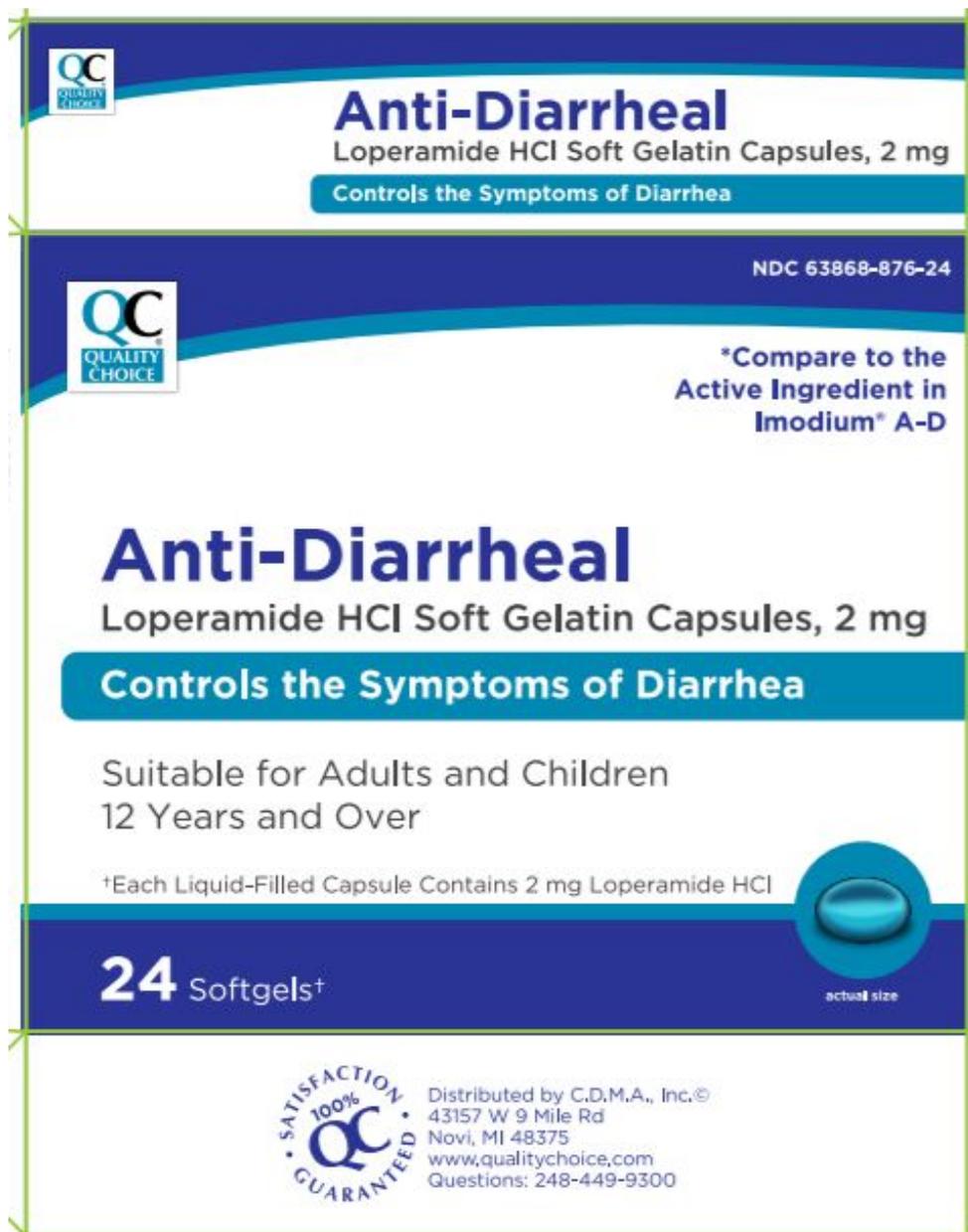
43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Questions: 248-449-9300

Principal Display Panel



The image shows the principal display panel for Anti-Diarrheal capsules. It features a blue and white color scheme with a green border. At the top left is the QC Quality Choice logo. The main title is "Anti-Diarrheal" in large blue font, followed by "Loperamide HCl Soft Gelatin Capsules, 2 mg" and a blue banner that says "Controls the Symptoms of Diarrhea". Below this, the NDC number "NDC 63868-876-24" is printed. A comparison statement reads: "*Compare to the Active Ingredient in Imodium® A-D". The product name "Anti-Diarrheal" is repeated in a larger font, followed by "Loperamide HCl Soft Gelatin Capsules, 2 mg" and another blue banner: "Controls the Symptoms of Diarrhea". Below this, it states "Suitable for Adults and Children 12 Years and Over". A footnote says "†Each Liquid-Filled Capsule Contains 2 mg Loperamide HCl". At the bottom left, it says "24 Softgels†". On the right, there is a circular inset showing a blue softgel capsule with the text "actual size" below it. At the bottom, there is a circular seal that says "SATISFACTION 100% GUARANTEED" around the QC logo, and contact information: "Distributed by C.D.M.A., Inc. © 43157 W 9 Mile Rd Novi, MI 48375 www.qualitychoice.com Questions: 248-449-9300".

QC
QUALITY
CHOICE

Anti-Diarrheal

Loperamide HCl Soft Gelatin Capsules, 2 mg

Controls the Symptoms of Diarrhea

NDC 63868-876-24

*Compare to the
Active Ingredient in
Imodium® A-D

Anti-Diarrheal

Loperamide HCl Soft Gelatin Capsules, 2 mg

Controls the Symptoms of Diarrhea

Suitable for Adults and Children
12 Years and Over

†Each Liquid-Filled Capsule Contains 2 mg Loperamide HCl

24 Softgels†

actual size

SATISFACTION
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QC
GUARANTEED

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Drug Facts

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Do not use ■ if you have bloody or black stool ■ in children under 12 years of age

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■ a history of abnormal heart rhythm

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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
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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 toll free 1-888-235-2466

QC ®

QUALITY CHOICE

NDC 63868-876-24

*Compare to the Active Ingredient in Imodium® A-D

Anti-Diarrheal

Loperamide HCl Soft Gelatin Capsules, 2 mg

Controls the Symptoms of Diarrhea

Suitable for Adults and Children

12 Years and Over

†Each Liquid-Filled Capsule Contains 2 mg Loperamide HCl

24 Softgels †

ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-876
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 CAPRYLATE (UNII: TM2TZD4G4A)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	LP2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-876-12	1 in 1 CARTON	01/25/2019	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63868-876-24	2 in 1 CARTON	01/25/2019	
2		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	01/25/2019	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(63868-876)

Revised: 12/2022

CHAIN DRUG MARKETING ASSOCIATION INC.