

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled  
TOP CARE (Topco Associates LLC)**

-----  
***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
- 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 **1-888-423-0139**

†This product is not manufactured or distributed by the owners 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.

Scan here for more  
information or  
call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
©TOPCO BMAA0521

QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

✓ QUALITY GUARANTEED

L0000460

Lot #

Expiration Date

Rev # 06/21

## 24's carton

+TopCare™

health

NDC 36800-208-12

COMPARE TO

IMODIUM® A-D

ACTIVE INGREDIENT†

Anti-Diarrheal

LOPERAMIDE HCl

SOFT GELATIN CAPSULES, 2 mg

Controls the Symptoms

of Diarrhea

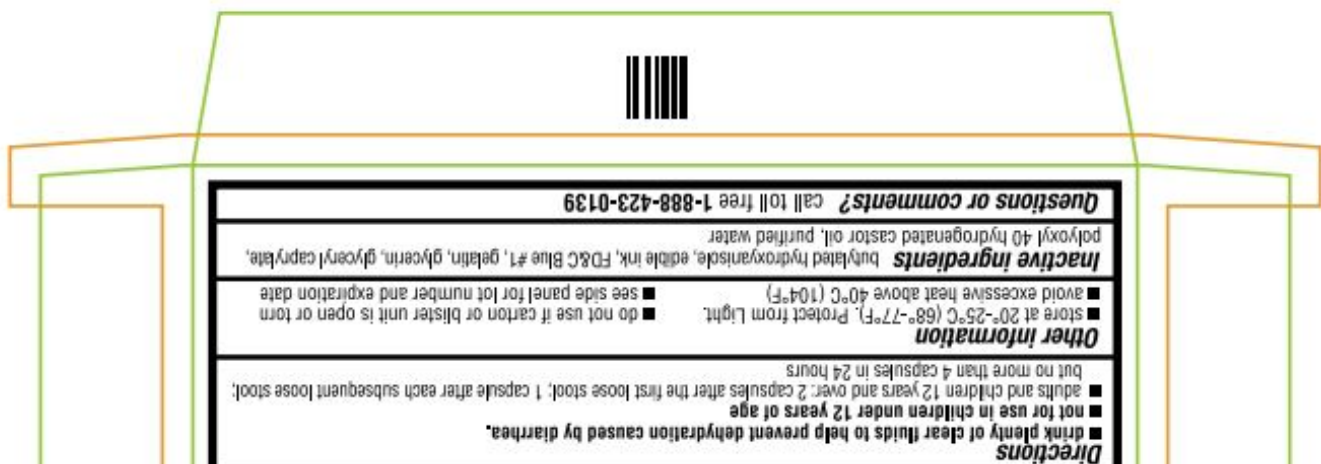
Suitable for Adults & Children

12 years and over

actual size

24 SOFTGELS\*

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



**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 ■ 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.



# Anti-Diarrheal

LOPERAMIDE HCl SOFT GELATIN CAPSULES, 2 mg

T00053



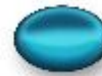
NDC 36800-208-12

COMPARE TO  
IMODIUM® A-D  
ACTIVE INGREDIENT†

# Anti-Diarrheal

LOPERAMIDE HCl  
SOFT GELATIN CAPSULES, 2 mg

- Controls the Symptoms of Diarrhea
- Suitable for Adults & Children 12 Years & Over



actual size

**24 SOFTGELS\***  
\*each liquid-filled capsule contains 2 mg Loperamide HCl

DISTRIBUTED BY TOPCO ASSOCIATES LLC  
ELK GROVE VILLAGE, IL 60007  
©TOPCO, BMA00521  
QUESTIONS? 1-888-423-0139  
topcare@topco.com  
www.topcarebrand.com



L0000460  
Lot #  
Expiration Date  
Rev # 06/21



# Anti-Diarrheal

LOPERAMIDE HCl SOFT GELATIN CAPSULES, 2 mg



Scan here for more information or call 1-888-423-0139

CAD#23336-A  
1



This product is not manufactured or distributed by the owners of Imodium® A-D

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TARIPTER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

## ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-208
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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 CAPRYLATE</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>	LP2
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-208-12	2 in 1 CARTON	07/02/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA021855	07/02/2021	

**Labeler** - TOP CARE (Topco Associates LLC) (006935977)**Registrant** - Bionpharma Inc. (079637826)

## Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(36800-208)

Revised: 12/2022

TOP CARE (Topco Associates LLC)