

**LOPERAMIDE HYDROCHLORIDE - loperamide hydrochloride capsule, liquid filled**  
**Aurohealth LLC**

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***Drug Facts***

***Active ingredient (in each capsule)***

Loperamide Hydrochloride USP, 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 hydrochloride

**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 (1-800-222-1222).

### ***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 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° to 25°C (68° to 77°F) [See USP controlled room temperature]. Protect from light.
- do not use if carton or blister unit is open or torn
- avoid excessive heat above 40°C (104°F)
- see side panel for lot number and expiration date
- FDA approved dissolution test specifications differ from USP.

### ***Inactive ingredients***

butylated hydroxyanisole, gelatin, glycerin, glyceryl monocaprylate, neelcert FD&C Blue No.1, polyoxyl 40 hydrogenated castor oil, purified water

### ***Questions or comments?***

call toll free **1-855-274-4122**

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg (24 Softgels) Blister  
Carton Label**

**AUROHEALTH**

**NDC 58602-727-76**

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

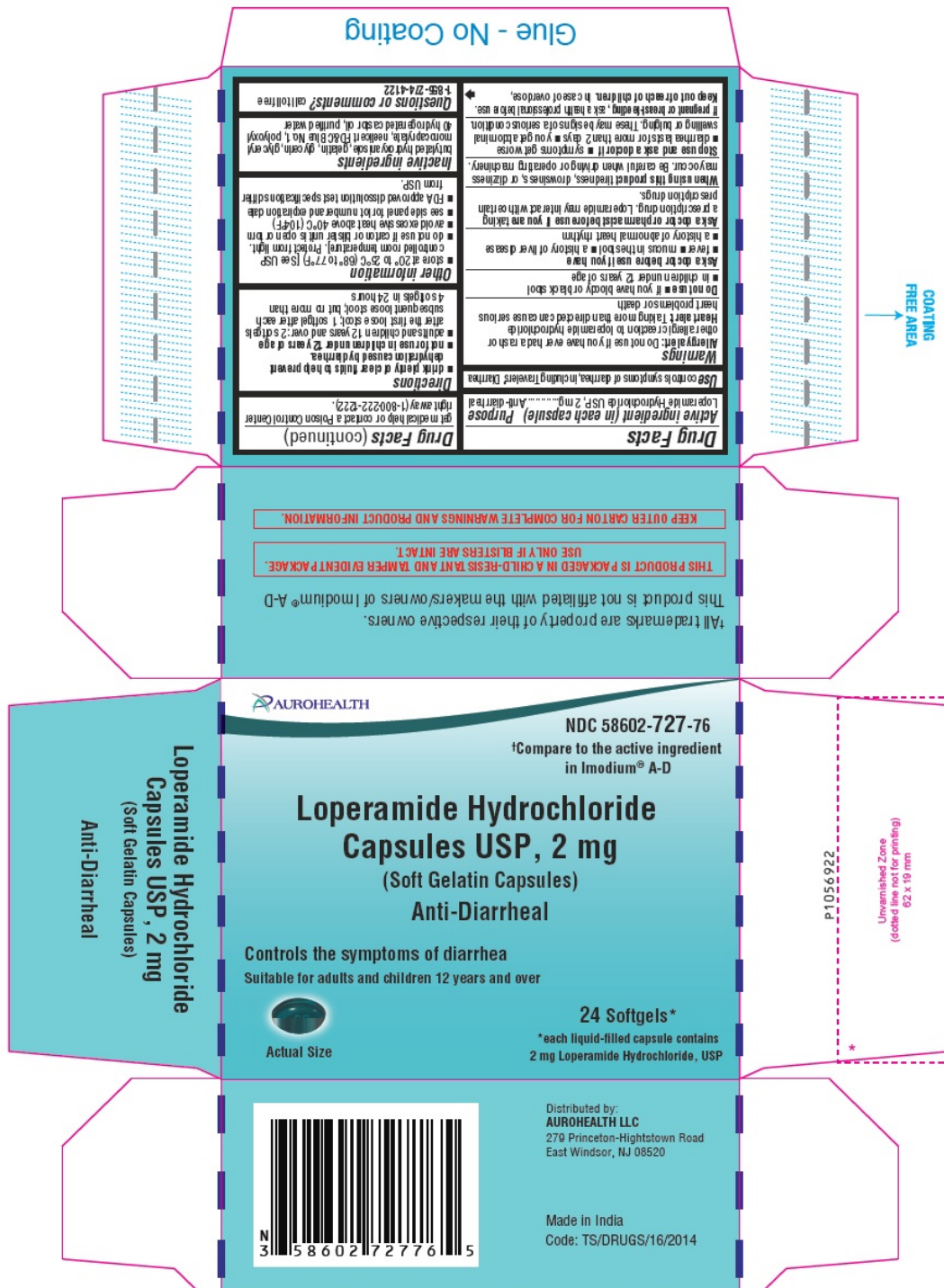
**Loperamide Hydrochloride  
Capsules USP, 2 mg  
(Soft Gelatin Capsules)  
Anti-Diarrheal**

**Controls the symptoms of diarrhea  
Suitable for adults and children 12 years and over**

**Actual Size**

**24 Softgels\***

**\*each liquid-filled capsule contains  
2 mg Loperamide Hydrochloride, USP**



\*Lot: XXXXXXXXX  
Exp.: YYYY-MMM  
Prefix, Variables of Lot, and Exp shall be printed online during packing.

## LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-727
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)				
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	BLUE (Pale blue to blue)	Score	no score	
Shape	OVAL	Size	10mm	
Flavor		Imprint Code	LO2	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-727-74	1 in 1 CARTON	12/29/2025	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-727-75	2 in 1 CARTON	12/29/2025	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-727-80	3 in 1 CARTON	12/29/2025	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:58602-727-76	4 in 1 CARTON	12/29/2025	
4		6 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
ANDA		ANDA220372	12/29/2025	

**Labeler** - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-727) , MANUFACTURE(58602-727)

Revised: 1/2026

Aurohealth LLC