

# **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, neelicert 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**

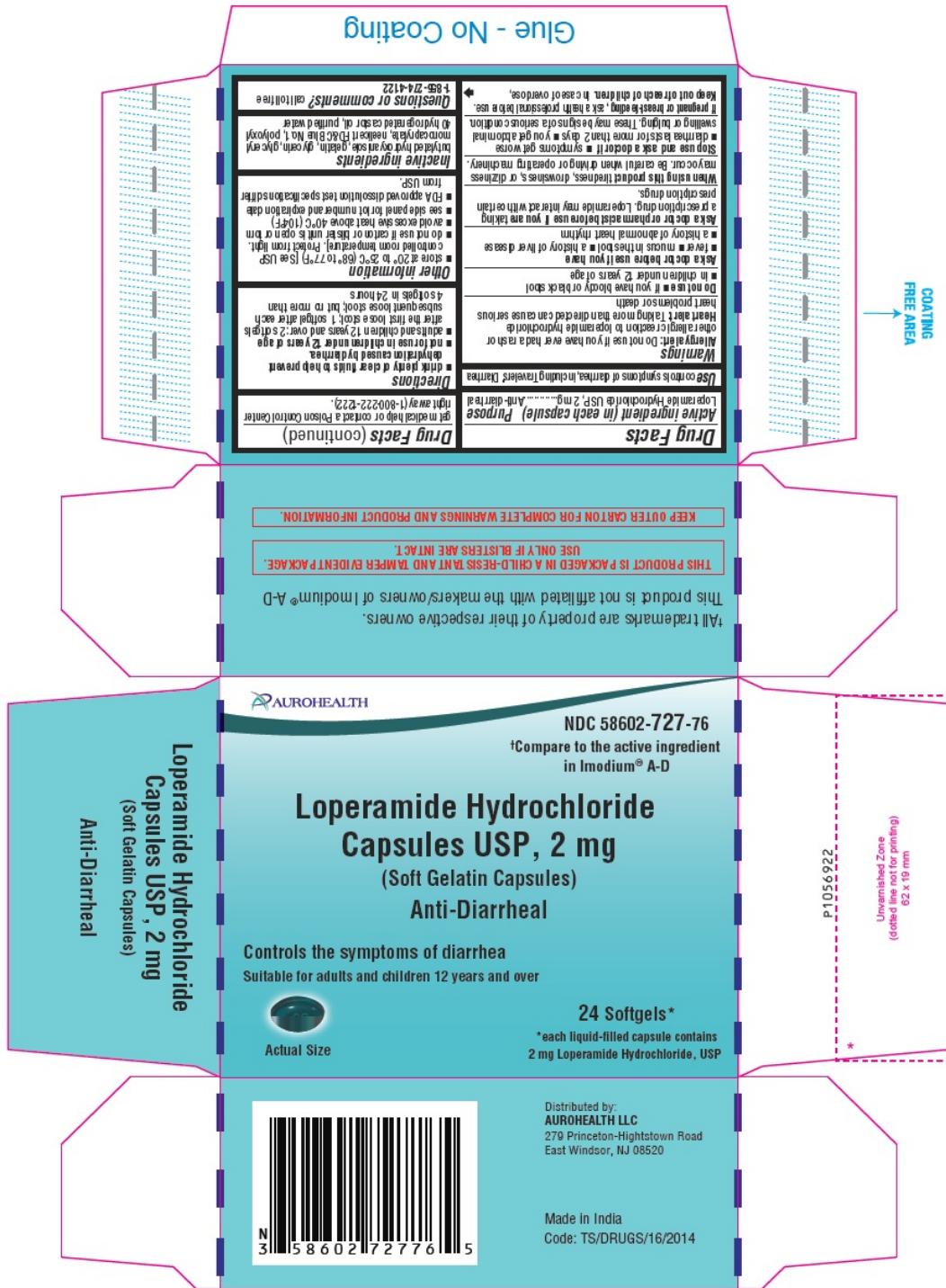
**Suitable for adults and children 12 years and over**

**Actual Size**

**24 Softgels\***

**\*each liquid-filled capsule contains**

**2 mg Loperamide Hydrochloride, USP**



# **LOPERAMIDE HYDROCHLORIDE**

## loperamide hydrochloride capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-727
<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>GELATIN TYPE B BOVINE (160 BLOOM)</b> (UNII: 1T8387508X)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>GLYCERYL MONOCAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	BLUE (Pale blue to blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	LO2
<b>Contains</b>			

## 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	

## Establishment

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

Revised: 1/2026

Aurohealth LLC