

**LOPERAMIDE HYDROCHLORIDE - loperamide hydrochloride tablet**  
**Aurohealth LLC**

-----

**Drug Facts**

**Active ingredient (in each tablet)**

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

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

**Directions**

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- find right dose on chart. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and over	2 tablets after the first loose stool; 1 tablet after each subsequent loose stool; but no more than 4 tablets in 24 hours
children 9 to 11 years (60 to 95 lbs)	1 tablet after the first loose stool; 1/2 tablet after each subsequent loose stool; but no more than 3 tablets in 24 hours
children 6 to 8 years (48 to 59 lbs)	1 tablet after the first loose stool; 1/2 tablet after each subsequent loose stool; but no more than 2 tablets in 24 hours
children 2 to 5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

**Other information**

- store at 20° to 25°C (68° to 77°F).
- **do not use if carton or blister unit is open or torn**
- Meets USP dissolution test 2
- See side panel for lot number and expiration date

**Inactive ingredients**

colloidal silicon dioxide, D & C yellow No. 10 aluminum lake, FD & C blue No. 1, lactose

monohydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate

**Questions or comments?**

call **1-855-274-4122**

Distributed by:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code .: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg Blister Carton (4 x 6's Tablets)**

**AUROHEALTH**

**NDC 58602-701-76**

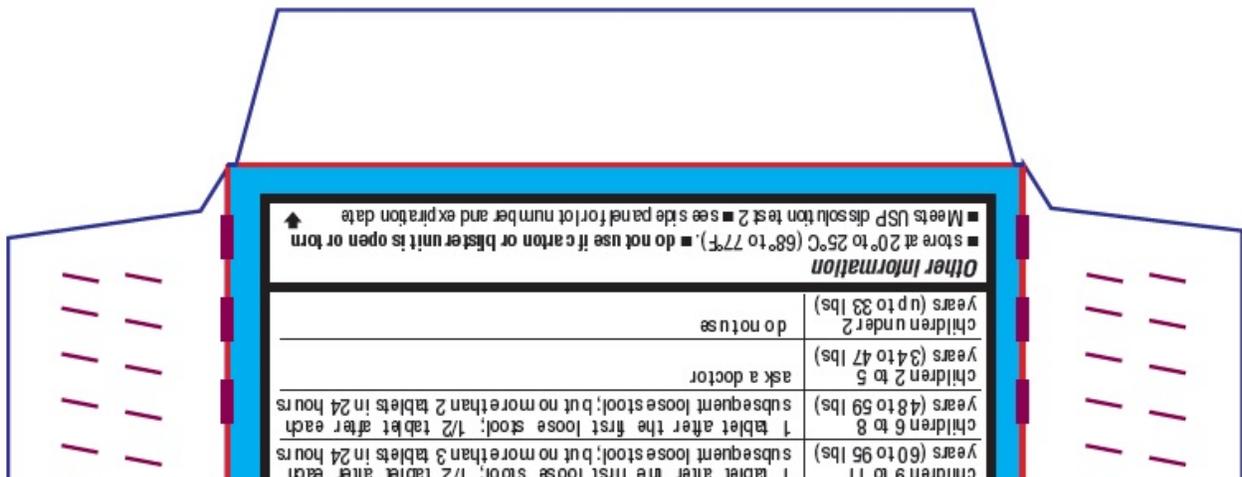
**\*Compare to the active ingredient of Imodium® A-D**

**Loperamide Hydrochloride Tablets USP 2 mg**

***Anti-Diarrheal***

***Controls the symptoms of diarrhea***

***24 Tablets***





**Drug Facts (continued)**

Do not use if you have bloody or black stool

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 bloating. 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 (1-800-222-1222) right away.

**Directions**

■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea

■ find right dose on chart. If possible, use weight to dose; otherwise, use age.

adults and children 2 tablets after the first loose stool; 1 tablet after each subsequent loose stool; but no more than 4 tablets in 24 hours

**Drug Facts**

**Active ingredient (in each tablet) Purpose**  
Loperamide hydrochloride USP 2 mg.....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

**Drug Facts (continued)**

Heart alert: Taking more than directed can cause serious heart problems or death



NDC 58602-701-76

\* Compare to the active ingredient of Imodium® A-D

# Loperamide Hydrochloride Tablets USP 2 mg

## Anti-Diarrheal

Controls the symptoms of diarrhea



24 Tablets



**Drug Facts (continued)**

**Inactive ingredients**  
colloidal silicon dioxide, D & C Yellow No. 10 aluminum lake, FD & C Blue No. 1, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate

**Questions or comments?** call 1-855-274-4122

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Imodium® A-D.

Distributed by:  
**AUROHEALTH LLC**  
279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Lot: LM-5207 P 1051570

EXP: NWZ

Made in India  
Code: TS/DRUGS/22/2009

# LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-701
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

## Product Characteristics

<b>Color</b>	GREEN (Light Green)	<b>Score</b>	2 pieces
<b>Shape</b>	CAPSULE (Biconvex)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	L;28
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-701-01	1 in 1 CARTON	12/15/2015	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58602-701-02	2 in 1 CARTON	12/15/2015	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:58602-701-76	4 in 1 CARTON	12/15/2015	

3	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206548	12/15/2015	

**Labeler** - Aurohealth LLC (078728447)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-701) , MANUFACTURE(58602-701)

Revised: 1/2025

Aurohealth LLC