

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

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***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)

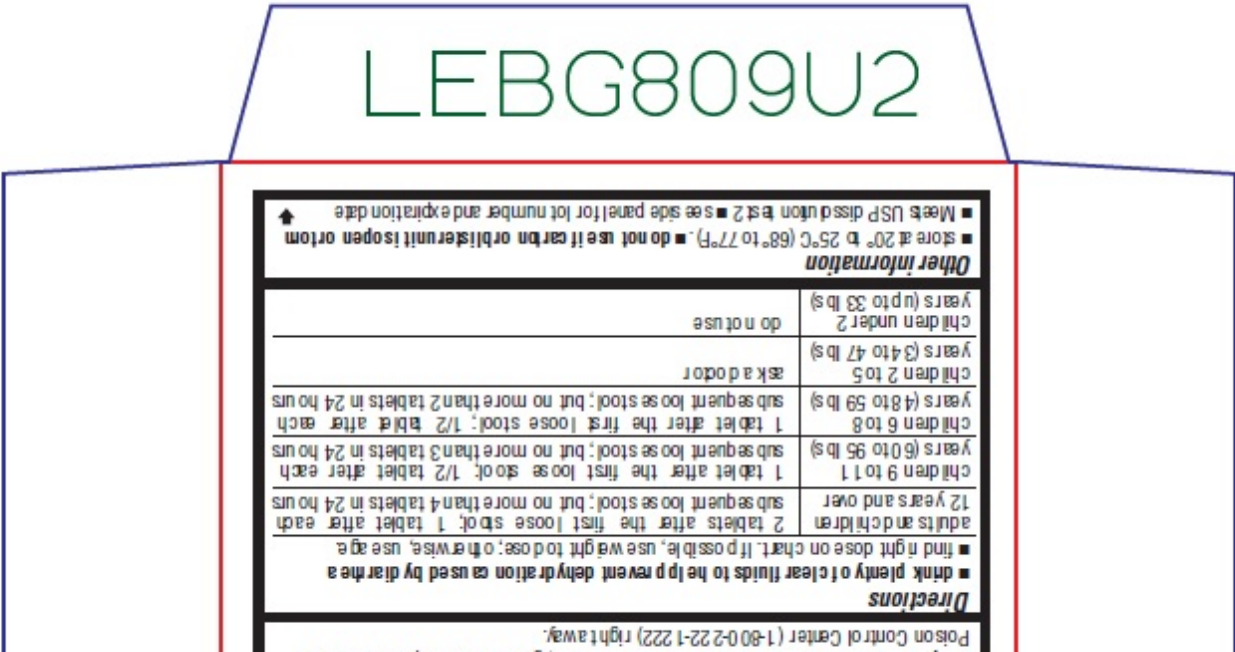
Healthy Living™

**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

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When using this product ■ redness, 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 breastfeeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a

**Drug Facts (continued)**

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

**Warnings**  
Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide hydrochloride

**Use**  
Controls symptoms of diarrhea, including travelers' diarrhea

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



# LOPERAMIDE

## hydrochloride tablets USP 2 mg

### Anti-Diarrheal



24 Tablets

Controls the symptoms of diarrhea

\*Compare to the Active Ingredient of Imodium® A-D

**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.

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**AUROHEALTH LLC**  
279 Princeton-Hightstown Road  
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LM-4500 P1043602

**NVZ**

Lot: EXP:

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

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-870
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	GREEN (Light Green)	Score	2 pieces
Shape	CAPSULE (Biconvex)	Size	10mm
Flavor		Imprint Code	L;28
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-870-76	4 in 1 CARTON	03/22/2022	
1		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	ANDA206548	03/22/2022	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-870) , MANUFACTURE(58602-870)

Revised: 3/2022

Aurohealth LLC