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

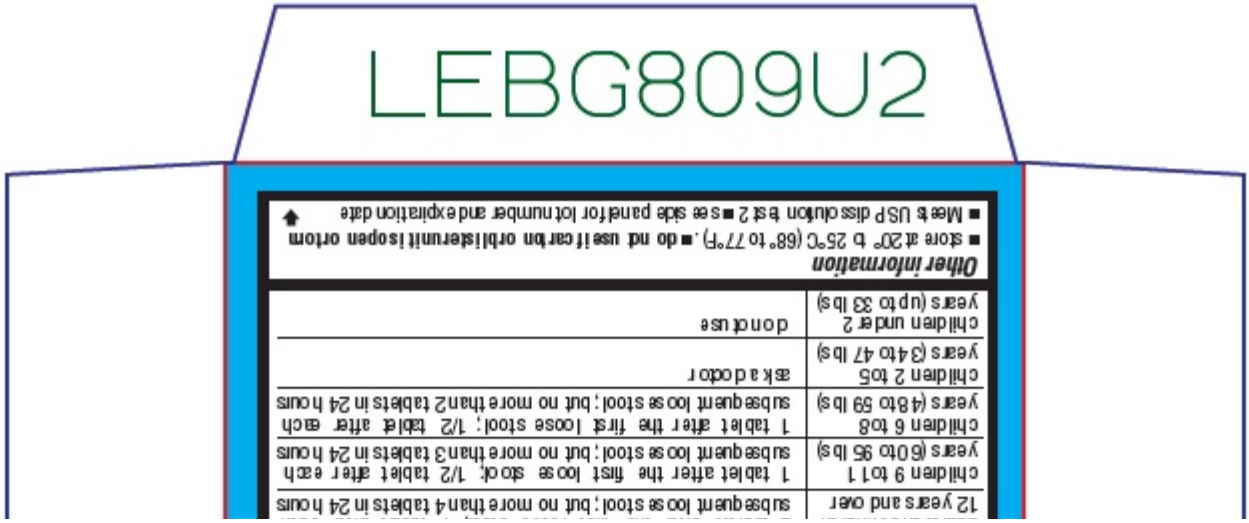
***Compare to the active ingredient of Imodium® A-D**

Loperamide Hydrochloride
Tablets USP 2 mg

Anti-Diarrheal

Controls the symptoms of diarrhea

24 Tablets



Drug Facts (continued)

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24 Tablets

Controls the symptoms of diarrhea

Anti-Diarrheal

Loperamide Hydrochloride Tablets USP 2 mg

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

NDC 58602-701-76

AUROHEALTH

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

LN-4555 P1043998

Lot:
EXP:

Drug Facts

Active ingredient (in each tablet) ***Purpose***

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Drug Facts (continued)

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Drug Facts (continued)

Do not use if you have bloody or black stool

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When using this product ill-ness, 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.

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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

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-701
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:58602-701-01	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		

3		Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206548	12/15/2015	

Labeler - Aurohealth LLC (078728447)

Establishment

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

Revised: 5/2021 Aurohealth LLC