

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet
Preferred Pharmaceuticals Inc.

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

Relabeled By: Preferred Pharmaceuticals Inc.

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

AUROHEALTH

Relabeled By: Preferred Pharmaceuticals Inc.

NDC 68788-8393

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

**Loperamide Hydrochloride
Tablets USP 2 mg**

Anti-Diarrheal

Controls the symptoms of diarrhea

24 Tablets

**Loperamide HCL
Tablets, USP 2mg**

Generic for Imodium

Each caplet contains: Loperamide HCL, USP 2 mg

Pkg Size: Exp Date: ####/###/####
Lot#: Batch#:

Ins:
Mfg: Aurohealth LLC
Prod#:

Warning

Store at 20°- 25°C (68°- 77°F). Keep this and all medications out of the reach of children, Rx Only. Please follow instructions on the back side of this blister card to open. Do not use if you have ever had a rash or other allergic reaction to loperamide HCL. Do not use if you have bloody or black stool.



Directions English

May cause drowsiness.
Take ___ tablet(s)
every ___ hours.



GTIN

SN #####
EXP ####/###/####

Instrucciones Espanol:

Puede causar
somnolencia.
Toma ___ tableta(s)
cada ___ horas.

CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed.

Loperamide HCL Tablets, USP 2mg
Qty: Ins:
Lot: Bat:
Prod# (NDC):

Loperamide HCL Tablets, USP 2mg
Qty: Ins:
Lot: Bat:
Prod# (NDC):

Loperamide HCL Tablets, USP 2mg
Qty:
Insurance NDC:
Lot: Bat:

Loperamide HCL Tablets, USP 2mg
Qty: Ins:
Lot: Bat:
Prod# (NDC):

Log
Chart
Billing
Patient

LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8393(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: 355W5USQ3G)	
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:68788-8393-2	4 in 1 CARTON	03/01/2023	
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	03/01/2023	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8393)

Revised: 7/2025

Preferred Pharmaceuticals Inc.