

LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution
Preferred Pharmaceuticals Inc.

Major Pharmaceuticals Loperamide Hydrochloride Oral Solution Drug Facts

Active ingredient (in each 7.5 mL)

Loperamide HCl 1 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 HCl

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

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.
- shake well before using
- use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.
- mL = milliliter

adults and children 12 years and over	30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours
children 9-11 years (60-95 lbs)	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours
children 6-8 years (48-59 lbs)	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 30 mL in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- **each 30 mL contains:** sodium 15 mg
- store between 20-25°C (68-77°F)

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, D&C yellow no. 10, FD&C blue no. 1, glycerin, microcrystalline cellulose, natural and artificial mint flavor, propylene glycol, purified water, simethicone, sodium benzoate, sucralose, titanium dioxide, xanthan gum

Questions or comments?

1-800-719-9260

Relabeled By: Preferred Pharmaceuticals Inc.

Package/Label Principal Display Panel

Compare to the active ingredient in Imodium® A-D

Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL

Anti-Diarrheal

Controls the symptoms of diarrhea

Mint Flavor - Anti-Diarrheal Oral Solution

4 FL OZ (120 mL)

SEE NEW WARNING AND DIRECTIONS

Loperamide Hydrochloride
Oral Solution 1mg /7.5mL

Generic for Imodium AD
Each 7.5mL contains: Loperamide HCl 1mg...
Anti-diarrheal

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

Ins:
Mfg: L. Perrigo Company
Prod#:
Warning

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl. Heart Alert: taking more than directed can cause heart problems or death. Do not use if you have ever had bloody or black stool. See bottle for additional drug facts, warnings and other information. Keep out of reach of children. Tamper Evident. Store between 20°-25°C (68°-77°F). Mint Flavor



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



GTIN #####
SN #####
EXP #####

Loperamide Hydrochloride Oral Solution 1mg/7.5mL
Qty: Ins:
Lot: Bat:
Prod# (NDC):

Loperamide Hydrochloride Oral Solution 1mg/7.5mL
Qty: Ins:
Lot: Bat:
Prod# (NDC):

Loperamide Hydrochloride Oral Solution 1mg/7.5mL
Qty:
Insurance NDC:
Lot: Bat:

Loperamide Hydrochloride Oral Solution 1mg/7.5mL
Qty: Ins:
Lot: Bat:
Prod# (NDC):

Log

Chart

Billing

Patient

Directions English

Take ___ teaspoonful(s) every ___ hours.
Use as directed by your doctor

Instrucciones Español:

Toma ___ cucharada(s) cada ___ horas
Uso según lo dirigido por su doctor

LOPERAMIDE HYDROCHLORIDE			
loperamide hcl solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7842(NDC:0904-6836)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)		LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL
Inactive Ingredients			
Ingredient Name			Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			

GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE, UNSPECIFIED (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	GREEN (opaque, viscous)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7842-1	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	01/19/2021	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-7842)