

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride solution
Carilion Materials Management

Drug Facts

Active ingredient

(in each 5 mL teaspoonful)

Loperamide HCl 1 mg

Purpose

Antidiarrheal

Uses

- controls the symptoms of diarrhea, including Traveler's Diarrhea

Warnings

Allergy alert: 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

Ask a doctor before use if you have

- high fever (greater than 101°F)
- mucus present in your stool
- a history of liver disease

Ask doctor or pharmacist before use if you are taking antibiotics

Stop use and ask a doctor if diarrhea lasts for more than 2 days

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.

Directions

- use enclosed dosage cup to accurately measure dosage as noted below
- drink plenty of clear fluids to help prevent dehydration, which may accompany diarrhea
- find right dose on chart. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and older	4 teaspoonfuls (1 dosage cup) after the first loose bowel movement; 2 teaspoonfuls (1/2 dosage cup) after each subsequent loose bowel movement; but no more than 8 teaspoonfuls a day
children 9-11 years (60-95 lbs)	2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; but no more than 6 teaspoonfuls a day
children 6-8 years (48-59 lbs)	2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; but no more than 4 teaspoonfuls a day

children under 6 years (up to 47 lbs) | ask a doctor (not intended for use in children under 6 years old)

Other information

- avoid excess heat
- store at room temperature, 15° - 30°C (59° - 86°F)

Inactive ingredients

alcohol (0.5%), benzoic acid, cherry flavor, glycerin, mint flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose. Citric acid may be used to adjust pH

Questions or comments?

Call **1-800-262-9010**

Mon. - Thurs. 9:00 am - 4:30 pm EST,

Fri. 9:00 am - 2:30 pm EST

Serious side effects associated with use of this product may be reported to this number.

Manufactured by:

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev. 618:05 4/12

HOW SUPPLIED

Product: 68151-0618

NDC: 68151-0618-1 1 mL in a SYRINGE, PLASTIC

LOPERAMIDE HYDROCHLORIDE SOLUTION

mfg:Hi-Tech
lot:355654

Loperamide HCL
Oral Solution
2MG/10ML
10mL oral syringe
PDM 0868
Delivers 10 ml

EXP:05/18
W112517Jm3
NDC:50383-618-04



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68151-0618(NDC:50383-618)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4I)	LOPERAMIDE HYDROCHLORIDE	1 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CHERRY (UNII: BUC5I9595W)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINT (UNII: FV98Z8GITP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68151-0618-1	1 mL in 1 SYRINGE, PLASTIC; Type 0: Not a Combination Product	12/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074352	11/17/1995	

Labeler - Carilion Materials Management (079239644)

Establishment

Name	Address	ID/FEI	Business Operations
Carilion Materials Management		079239644	REPACK(68151-0618)

