

LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride solution
Atlantic Biologicals Corps

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

Do not use if you have ever had a rash or other allergic reaction to loperamide HCl **Allergy alert:**
if you have bloody or black stool **Do not use**

Ask a doctor before use if you have

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

taking antibiotics **Ask doctor or pharmacist before use if you are**
diarrhea lasts for more than 2 days **Stop use and ask a doctor if**
, ask a health professional before use **If pregnant or breast-feeding**

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.

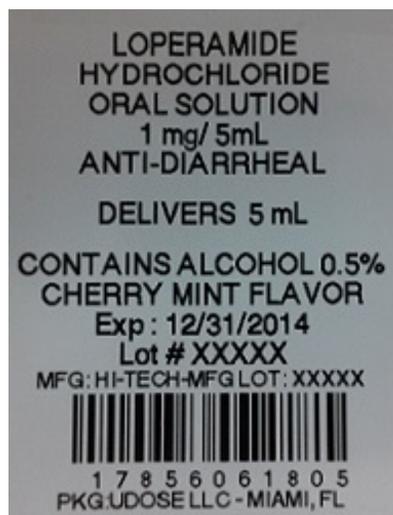
Manufactured by:

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev. 618:05 4/12

LOPERAMIDE HYDROCHLORIDE SOLUTION



LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0618(NDC:50383-618)
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 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: FV98Z8G1TP)	
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:17856-0618-1	10 mL in 1 CUP; Type 0: Not a Combination Product	10/16/2019	
2	NDC:17856-0618-5	5 mL in 1 CUP; Type 0: Not a Combination Product	10/16/2019	

Marketing Information

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

Labeler - Atlantic Biologicals Corps (047437707)

Registrant - Atlantic Biologicals Corps (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-0618) , REPACK(17856-0618)

