GOOD NEIGHBOR PHARMACY LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution

ATLANTIC BIOLOGICALS CORP.

Amerisource Bergen Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL 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

Ask a doctor or pharmacist before use if you are

taking antibiotics

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

	30 mL after the first loose stool; 15 mL after each subsequent loose stool; but no more than 60 mL in 24 hours
,	15 mL after the first loose stool; 7.5 mL after each subsequent loose stool; but no more than 45 mL in 24 hours
,	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?

DISTRIBUTED BY: ATLANTIC BIOLOGICALS CORP.20101 N.E 16TH PLACE MIAMI, FL 33179

1-800-719-9260

Package/Label Principal Display Panel

Compare to Imodium® A-D active ingredient

See New Warning and Directions

Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL

anti-diarrheal

Controls the Symptoms of Diarrhea mint flavor anti-diarrheal oral solution

17856-0545-01 LOPERAMIDE HCL Oral Solution 2 MG/15 mL



Rev.01/19

See package insert for indications and dosage schedule

Store between 20-25°C (68-77°F); Each 30mL contains: sodium 15 mg
ANTI-DIARRHEAL MINT FLAVOR

**** Keep this and all Medication out of the reach of children

17856-0545-01

Dosage: 15 mL Cup

LOPERAMIDE

Qty: 50 Cups

GTIN: 00117856054511

S/N: 00000000000001

Exp: 01/23/20 Lot: 000000 OTC

17856054501

Packaged by:Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp, Miami FI 33179

Call to Reorder: 800.509.7592

17856-0545-02 LOPERAMIDE HCL Oral Solution 1 MG/7.5 mL



3ev.01/19

See package insert for indications and dosage schedule

Store between 20-25°C (68-77°F); Each 30mL contains; sodium 15 mg
ANTI-DIARRHEAL MINT FLAVOR
**** Keep this and all Medication out of the reach of children

17856-0545-02

Dosage: 7.5 mL

LOPERAMIDE

Qty: 72 Cups

GTIN: 00117856054528 S/N: 000000000000001

Exp: 01/23/20 Lot: 000000 OTC



Packaged by:Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlanticBiologicals

Corp, Miami FI 33179

Call to Reorder: 800.509.7592

GOOD NEIGHBOR PHARMACY LOPERAMIDE HYDROCHLORIDE

loperamide hcl solution

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:17856-0545(NDC:46122-544)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDRO CHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6 X9 OC3H4II)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

Inactive Ingredients	
Ingredient Name	Strength

ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
SILICON DIO XIDE (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:17856-0545- 2	72 in 1 BOX, UNIT-DOSE	01/22/2021	
1		7.5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0545-1	50 in 1 BOX, UNIT-DOSE	01/22/2021	
2		15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	08/13/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-0545), relabel(17856-0545)

Revised: 1/2021 ATLANTIC BIOLOGICALS CORP.