# GOOD NEIGHBOR PHARMACY LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution

ATLANTIC BIOLOGICALS CORP.

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### 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: ETJ7Z6 XBU4)	

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:17856-0545- 2	72 in 1 BOX, UNIT-DOSE	07/24/2019		
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	07/24/2019		
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)