

**LOPERAMIDE HYDROCHLORIDE- loperamide hcl solution**  
**ATLANTIC BIOLOGICALS CORP.**

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**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?

## DISTRIBUTED BY:

**ATLANTIC BILOGICALS CORP.**  
**20101 N.E 16TH PLACE**  
**MIAMI, FL 33179**  
**1-800-719-9260**

## Package/Label Principal Display Panel

Compare to the active ingredient in Imodium® A-D

17856-6836-1 Loperamide Hydrochloride Oral Solution, 1 mg per 7.5 mL

17856-6836-2 Loperamide Hydrochloride Oral Solution, 2 mg per 15 mL

Anti-Diarrheal

Controls the symptoms of diarrhea

Mint Flavor - Anti-Diarrheal Oral Solution

SEE NEW WARNING AND DIRECTIONS

**17856-6836-01**

Loperamide Hydrochloride  
Oral Solution

1mg/7.5mL

Delivers 7.5mL



See package insert for indications and dosage schedule

Store between 20°-25°C (68°-77°F)  
KEEP OUT OF THE REACH OF CHILDREN



17856-6836-01

Dosage: 1mg/7.5mL

Loperamide Hydrochloride

Qty: 72 CUPS



GTIN: 00117856683612

S/N: 01018301

Exp: 10/21/20

Lot: 010183

OTC

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.  
Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

**17856-6836-02**  
**Loperamide Hydrochloride**  
**Oral Solution**  
**2mg/15mL**  
**Delivers 15mL**



See package insert for indications and dosage schedule



Store between 20°-25°C (68°-77°F)  
KEEP OUT OF THE REACH OF CHILDREN

17856-6836-02

Dosage: 2mg/15mL

Loperamide Hydrochloride Qty: 50 CUPS



GTIN: 00117856683629

S/N: 01018801

Exp: 10/21/20

Lot: 010188

OTC

Packaged by Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.  
Miami Fl 33179

Rev 09/19

**Call to Reorder: 800.509.7592**

**LOPERAMIDE HCL  
2 MG/15 ML  
ORAL SUSPENSION  
ANTI-DIARRHEAL  
DELIVERS 15 ML**



17856683602

**DISTRIBUTED BY ATLANTIC  
BIOLOGICALS CORP.**

Exp:04/21/2020

Lot#lot1

Mfg:DIST:MAJOR MFG LOT#XXXXXX  
Pkg by UDS  
Morrisville, NC 27560

**LOPERAMIDE HCL  
1 MG/7.5 ML  
ORAL SUSPENSION  
ANTI-DIARRHEAL  
DELIVERS 7.5 ML**



17856683601

**DISTRIBUTED BY ATLANTIC  
BIOLOGICALS CORP.**

Exp:04/21/2020

Lot#lot1

Mfg:DIST:MAJOR MFG LOT#XXXXXX  
Pkg by UDS  
Morrisville, NC 27560

## LOPERAMIDE HYDROCHLORIDE

loperamide hcl solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-6836(NDC:0904-6836)
<b>Route of Administration</b>	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 FORM (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)	

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	GREEN (opaque, viscous)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-6836-1	72 in 1 BOX, UNIT-DOSE	04/21/2020	
1		7.5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-6836-2	50 in 1 BOX, UNIT-DOSE	04/21/2020	
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	11/29/2018	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)

### Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-6836) , relabel(17856-6836)

Revised: 4/2020

ATLANTIC BIOLOGICALS CORP.