

## **LOPERAMIDE HYDROCHLORIDE- loperamide hcl liquid**

### **Major Pharmaceuticals**

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### **Major Pharmaceuticals Loperamide Hydrochloride Oral Suspension 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

#### **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
- only use attached measuring cup to dose product

adults and children 12 years and over	30 mL (6 tsp) after the first loose stool; 15 mL (3 tsp) after each subsequent loose stool; but no more than 60 mL (12 tsp) in 24 hours
children 9-11 years (60-95 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 45 mL (9 tsp) in 24 hours
children 6-8 years (48-59 lbs)	15 mL (3 tsp) after the first loose stool; 7.5 mL (1 1/2 tsp) after each subsequent loose stool; but no more than 30 mL (6 tsp) in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

## Other Information

- each 30 mL (6 tsp) contains: sodium 15 mg
- store between 20-25°C (68-77°F)
- see side panel for lot number and expiration date

## 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?

1-800-719-9260

## Package/Label Principal Display Panel

Loperamide Hydrochloride Oral Suspension

Anti-Diarrheal Liquid

Controls the Symptoms of Diarrhea

Mint Flavor

4 FL OZ (120 mL)

1 mg Loperamide Hydrochloride per 7.5 mL

COMPARE TO the active ingredient in IMODIUM® A-D

**Drug Facts**

**Active ingredient Purpose (in each 7.5 mL)**  
Loperamide HCl  
1 mg.....Anti-diarrheal

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**PEEL BACK HERE**

**MAJOR**® NDC 0904-6256-20

**Loperamide Hydrochloride Oral Suspension**

Anti-Diarrheal Liquid

Controls the Symptoms of Diarrhea

Mint Flavor

4 FL OZ (120 mL)

1 mg Loperamide Hydrochloride per 7.5 mL

COMPARE TO the active ingredient of **IMODIUM® A-D\***

Do not use if printed plastic neckband is broken or missing

\*Major® Loperamide Hydrochloride Oral Suspension is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Imodium® A-D.  
Distributed by: **MAJOR® PHARMACEUTICALS**  
31778 Enterprise Drive, Livonia, MI 48150 USA  
M-05 REV. 09/13  
Re-Order No. 700606

**Gluten Free**



: 64526 5C F2

**Drug Facts (continued)**

**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.

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■ 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

**Drug Facts (continued)**

Control Center right away. (1-800-222-1222)

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**Drug Facts (continued)**

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**Drug Facts (continued)**

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**Questions or comments?**  
1-800-719-9260

# LOPERAMIDE HYDROCHLORIDE

loperamide hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0904-6256
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77T35393C) (LOPERAMIDE - UNII:6X9OC3H4I)	LOPERAMIDE HYDROCHLORIDE	1 mg in 7.5 mL

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

## 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:0904-6256-20	120 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091292	03/14/2012	

