

**GADAVYT LOPERAMIDE HCL - loperamide hydrochloride liquid**  
**Gadal Laboratories Inc**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Drug Facts**

| <b>Active Ingredient (in each 5mL teaspoonful)</b> | <b>Purpose</b> |
|--|----------------|
| Loperamide HCl, 1mg .....                          | Antidiarrheal  |

**Purpose**

**Antidiarrheal**

**Uses**

controls the symptoms of diarrhea, including Traveler's 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

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

**Ask a doctor or pharmacist before use if you are** taking antibiotics

**Stop use and ask a doctor if diarrhea lasts for more than 2 days**

**Keep out of reach of children.** In case of overdose, get medical help or contact Poison Control Center right away.

**If pregnant or breast-feeding,**ask a health professional before use

**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 dosage 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;<br>2 teaspoonfuls (1/2 dosage cup) after each subsequent loose bowel movement;<br>but no more than 8 teaspoonfuls a day  |
| Children 9-11 (60-95 lbs)              | 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement;<br>1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement;<br>but no more than 6 teaspoonfuls a day |
|  | 2 teaspoonfuls (1/2 dosage cup) after the first loose bowel movement;  |

|                                       |  |
|---------------------------------------|--|
| Children 6-8 (48-59 lbs)              | 1 teaspoonfuls (1/4 dosage cup) after each subsequent loose bowel movement;<br>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)  |

### Inactive ingredients

citric acid, propylene glycol, methylparaben, propylparaben, glycerin, sucralose, cherry flavor, peppermint flavor, sorbitol, purified water

### Questions or comments?

Call 305-382-3288

www.gadalaboratories.com

**Tamper evident:** do not use this product if the safety seal around the neck or under the cap is broken or missing

| Drug Facts   |   |
|--|---|
| <b>Active ingredient</b> (in each 5ml teaspoonful)   | <b>Purpose</b><br>Loperamide HCl, 1mg.....Antidiarrheal |
| <b>Uses</b> • controls the symptoms of diarrhea, including Traveler's Diarrhea.  |   |
| <b>Warnings</b>  |   |
| <b>Allergy Alert:</b> Do not use if you have ever had a rash or other allergic reaction to Loperamide HCl.   |   |
| <b>Do not use</b> if you have bloody or black stool  |   |
| <b>Ask a Doctor before use</b> if you have • high fever (greater than 101°F) • mucus present in your stool • a history of liver disease  |   |
| <b>Ask a doctor or pharmacist before use</b> if you are • taking antibiotics   |   |
| <b>Stop use and ask a doctor if</b> • diarrhea lasts for more than 2 days  |   |
| <b>If pregnant or breast-feeding,</b> ask a health professional before use   |   |
| <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.   |   |
| <b>Directions</b> 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 dosage on chart • if possible, use weight to dose; otherwise, use age. |   |

**Drug Facts** (continued)

|  |  |
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**Other information** • avoid excess heat • store at room temperature, 15°-30°C (59°-89°F)

**Inactive Ingredients** citric acid, propylene glycol, methylparaben, propylparaben, glycerin, sucralose, cherry flavor, peppermint flavor, sorbitol, purified water.

**Questions, or comments?**  
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NDC 53113-657-04

**Loperamide HCl**  
**ANTI-DIARRHEAL**

**Oral Solution**

To control the symptoms of Diarrhea, including Traveler's Diarrhea

**1 mg / 5 mL**  
Convenient dosage cup enclosed

**4 fl oz (118 mL)**

**CHERRY MINT FLAVOR**

**GADAL LABORATORIES**  
Miami, FL 33186



**Loperamide HCl**  
**ANTI-DIARRHEAL**

**Oral Solution**

To control the symptoms of Diarrhea, including Traveler's Diarrhea

**1 mg / 5 mL**  
Convenient dosage cup enclosed.

**CHERRY MINT FLAVOR**

**RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**DO NOT USE THIS PRODUCT IF THE SAFETY SEAL AROUND THE NECK OR UNDER THE CAP IS BROKEN OR MISSING**

See lower panel for expiration date.

## GADAVYT LOPERAMIDE HCL

loperamide hydrochloride liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53113-657 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength           | Strength        |
|--|-----------------------------|-----------------|
| LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II) | LOPERAMIDE<br>HYDROCHLORIDE | 1 mg<br>in 5 mL |

**Inactive Ingredients**

| Ingredient Name                            | Strength |
|--|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)        |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)           |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)           |          |
| GLYCERIN (UNII: PDC6A3C0OX)                |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)               |          |
| SORBITOL (UNII: 506T60A25R)                |          |
| WATER (UNII: 059QF0KO0R)                   |          |

**Product Characteristics**

|          |                               |              |  |
|----------|-------------------------------|--------------|--|
| Color    |                               | Score        |  |
| Shape    |                               | Size         |  |
| Flavor   | CHERRY (Cherry) , MINT (Mint) | Imprint Code |  |
| Contains |                               |              |  |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:53113-657-04 | 1 in 1 CARTON       |                      |                    |
| 1 |                  | 118 mL in 1 BOTTLE  |                      |                    |

**Marketing Information**

| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| unapproved drug other |  | 05/01/2013           |                    |

**Labeler** - Gadal Laboratories Inc (841305639)

Revised: 5/2013

Gadal Laboratories Inc