#### 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**

Active Ingredient (in each 5mL teaspoonful)	Purpose

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 fiver (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; 2 teaspoonfuls (1/2 dosage cup) after each subsequent loose bowel movement; 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; 1 teaspoonful (1/4 dosage cup) after each subsequent loose bowel movement; 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;
	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

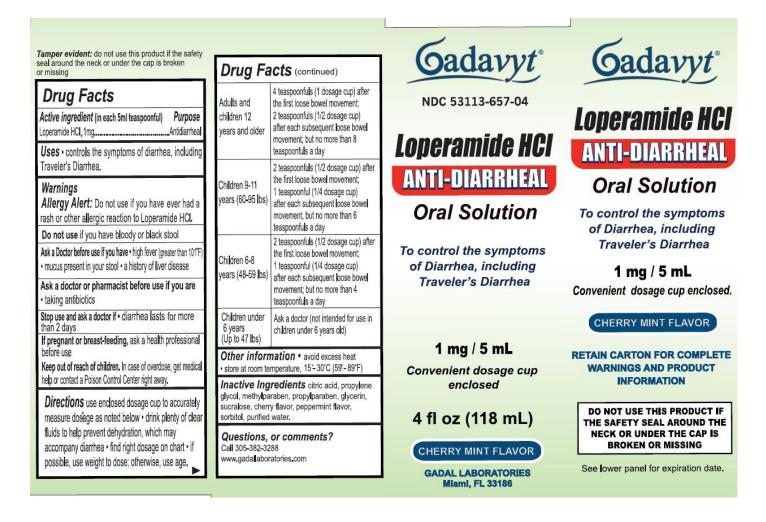
#### **Inactive ingredients**

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

#### Questions or comments?

Call 305-382-3288

www.gadallaboratories.com



## GADAVYT LOPERAMIDE HCL

loperamide hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-657
Route of Administration	ORAL		

	Active Moiety					
	Ingredient Name			Basis of S	trength	Strengtl
LOPERAMIDE HYDROC UNII:6 X9 OC 3H4II)	HLORIDE (UNII: 77TI35393C) (LOPEI	RAMIDE -		LOPERAMIDE HYDROCHLORIDE		1 mg in 5 mL
Inactive Ingredient						
CITRIC ACID MONOLIN	Ingredient Nam	e			S	trength
	DRATE (UNII: 2968PHW8QP)					
PROPYLENE GLYCOL ( METHYLPARABEN (UNI						
PROPYLPARABEN (UNI						
GLYCERIN (UNII: PDC6A						
SUCRALOSE (UNII: 96K)						
SORBITOL (UNII: 506T6						
WATER (UNII: 059QF0K						
Calar			Score Size			
Shape	HERRY (Cherry) , MINT (Mint)				le	
Shape Flavor C	HERRY (Cherry) , MINT (Mint)			Size	le	
Color Shape Contains Contains Packaging	HERRY (Cherry) , MINT (Mint)			Size	le	
Shape Graver Contains	HERRY (Cherry) , MINT (Mint) Package Description	Marketin	g Start Da	Size Imprint Coo	le Marketing 1	End Date
Shape Contains Code Hermited Stresson Shape Shape Contains Contains Code Hermited Stresson Shape		Marketin	g Start Da	Size Imprint Coo		End Date
Shape Contains Conta	Package Description	Marketin	g Start Da	Size Imprint Coo		End Date
Shape Flavor C Contains C Packaging MDC:53113-657-04 1 NDC:53113-657-04 1 NDC:557-04 1 ND	Package Description1 in 1 CARTON118 mL in 1 BOTTLE	Marketin	g Start Da	Size Imprint Coo		End Date
Shape Contains Contains	Package Description1 in 1 CARTON118 mL in 1 BOTTLE			Size Imprint Coo	Marketing 1	End Date

# Labeler - Gadal Laboratories Inc (841305639)

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Gadal Laboratories Inc