

**LOPERAMIDE HYDROCHLORIDE- loperamide hydrochloride tablet, film coated**  
**Central Texas Community Health Centers**

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**Loperamide hydrochloride**

**Active ingredient (in each caplet)**

Loperamide HCl 2 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.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children under 6 years (up to 47 lbs)	ask a doctor

### Other information

- store at 20°-25°C (68°-77°F)
- do not use if printed foil under cap is broken or missing
- see end panel for lot number and expiration date

### Inactive ingredients

anhydrous lactose, carnauba wax, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

### PRINCIPAL DISPLAY PANEL - 2 MG Tablet Blister Pack Carton Label

CommUnityCare Federally Qualified Health Centers

LOPERAMIDE

2MG Tablet

#12

Date:

Name:

Dr.

TAKE AS DIRECTED.

123456

1/1/01

LOPERAMIDE 2MG Tablet #12 NDC 76413-314-12

Batch: 123456

Lot: 123456

Exp: 1/1/01

SUNMARK

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

LOPERAMIDE  
2MG Tablet  
#12

Date:

Name:

Dr.

TAKE AS DIRECTED.

TOME COMO INDICADO.

123456

1/1/01

LOPERAMIDE 2MG Tablet #12 NDC 76413-314-12

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Lot: 123456

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## LOPERAMIDE HYDROCHLORIDE

loperamide hydrochloride tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-314(NDC:49348-529)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

### Product Characteristics

Color	GREEN	Score	2 pieces
Shape	CAPSULE	Size	10 mm
Flavor		Imprint Code	L2
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-314-12	2 in 1 CARTON	06/27/2003	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075232	06/27/2003	

**Labeler** - Central Texas Community Health Centers (079674019)

## Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-314) , RELABEL(76413-314)

Revised: 4/2016

Central Texas Community Health Centers