

**ANTI-DIARRHEAL- loperamide hcl tablet**  
**Northeast Pharma**

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**HPC 381**

**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

**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**

- a fever
- mucus present in your 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**

- diarrhea lasts for more than 2 days
- symptoms get worse
- 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.

## 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 2-5 years (34-47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

## Other Information

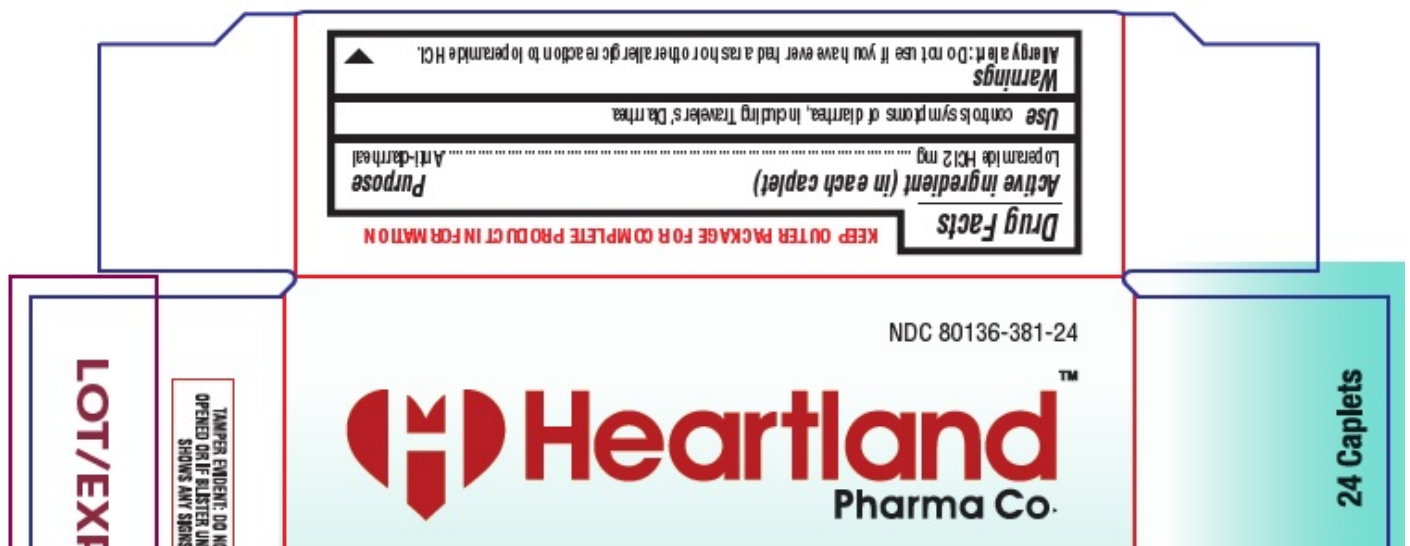
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store between 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

## Inactive Ingredients

corn starch, D&C yellow #10 lake, dibasic calcium phosphate dihydrate, FD&C blue #1 lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

**Questions or comments?** call 1-800-540-3765

## package Label



# ANTI-DIARRRHEAL

Loperamide HCl Tablets, 2 mg  
Anti-Diarrheal

Controls the symptoms  
of Diarrhea



Actual Size

Compare to active  
ingredient in **IMODIUM® A-D\***

## 24 Caplets



**ANTI-DIARRRHEAL**  
Loperamide HCl Tablets, 2 mg

USE IF PACKAGE IS  
TORN, BROKEN OR  
MISCELLANEOUS



B-0617-375-08HP  
OR03061937508



1. To open, tear at perforations and through plastic for caplet.



2. Use scissor to cut remove a section.

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark **Imodium® A-D**.  
50844 OR061937508  
REV 0321  
Distributed By: NortheastPharma  
South Burlington, VT 05403 1-800-383-0648  
www.heartlandpharmaco.com

**Drug Facts (continued)**

Heartland: 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 a fever, a fever, mucus in the stool, or a history of liver disease.  
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, dizziness, tiredness, or weakness 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, or you get abdominal swelling or bloating. These may be signs of a serious condition.  
If pregnant or breastfeeding, 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.

**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
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child under 2 years (up to 33 lbs)	do not use

**Other information**  
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTERS ARE TORN OR BROKEN  
■ Store between 20°-25°C (68°-77°F). ■ See end flap for expiration date and lot number

**Inactive ingredients** corn starch, D & C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD & C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

**Questions or comments?** Call 1-800-540-3765



# ANTI-DIARRHEAL

loperamide hcl tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80136-381
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
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

## Product Characteristics

Color	green (light green)	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	44;375
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-381-24	4 in 1 CARTON	09/01/2020	
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	ANDA076497	09/01/2020	

**Labeler** - Northeast Pharma (081232935)

**Registrant** - Geri-Care Pharmaceutical Corp (611196254)

Revised: 4/2021

Northeast Pharma