

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

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**Heartland Pharma 44-375**

***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 in the 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**

- 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.

**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 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

**Questions or comments?**

**Call 1-800-426-9391** 8:30 AM-4:00 PM ET, Monday-Friday

**Principal Display Panel**

NDC 80136-063-11

Heartland™  
Pharma Co.

**ANTI-DIARRHEAL**  
**Loperamide HCl Tablets, 2 mg**  
**Anti-Diarrheal**

Controls the symptoms  
of Diarrhea

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

**24 Caplets**

Actual Size

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS  
OPENED OR IF BLISTER UNIT IS TORN, BROKEN  
OR SHOWS ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by Johnson &  
Johnson Corporation, owner of the registered trademark  
Imodium® A-D 50844 ORG061937508

Distributed by:

**NORTHEAST PHARMA**  
South Burlington, VT 05403  
www.heartlandpharmaco.com  
1-800-383-0648

1. To open, tear at perforations and remove a section.
2. Use ✂ to cut through plastic for caplet.



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## Anti-Diarrheal

# Controls the symptoms of Diarrhea



Actual Size

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

## 24 Caplets



### ANTI-DIARRHEAL

Loperamide HCl Tablets, 2 mg

B-0621-375-08  
090061937508



2. Use  $\pi$  to cut through plastic for caplet.



1. To open, tear at perforations and remove a section.

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Distributed by:  
**NORTHEAST PHARMA**  
South Burlington, VT 05403  
www.heartlandpharmaco.com  
1-800-383-0648

**Drug Facts (continued)**

**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 in the 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 ■ symptoms get worse ■ diarrhea lasts for more than 2 days ■ you get abdominal swelling or bugging. 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	loose stool; but no more than 4 caplets in 24 hours
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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 BUSTER 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 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

**Questions or comments?** Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Heartland 44-375

## ANTI-DIARRHEAL

loperamide hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80136-063
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>D&amp;C YELLOW NO. 10 ALUMINUM LAKE</b> (UNII: CQ3XH3DET6)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-063-11	4 in 1 CARTON	01/22/2021	
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	01/22/2021	

**Labeler** - Northeast Pharma (081232935)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(80136-063) , pack(80136-063)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(80136-063)

Revised: 4/2024

Northeast Pharma