

**ANTI-DIARRHEAL- loperamide hcl tablet**  
**Advanced Rx LLC**

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**PureGen 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**

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

**Other information**

- **each caplet contains:** calcium 15 mg
- **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**

**PUREGEN  
LABS**

Compare to the active ingredient  
in Imodium® A-D\*

NDC 80513-375-08

**ANTI-DIARRHEAL**

Loperamide HCl Tablets, 2 mg  
Anti-Diarrheal

Controls the symptoms of diarrhea

**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**

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

**2.** Use ✂ to cut  
through plastic  
for caplet.

\*This product is not manufactured or distributed by  
Kenvue Inc., owner of the registered trademark  
Imodium® A-D. 50844 REV0325A37508

Distributed by: **ADVANCED RX LLC**  
1942 NE 163rd St  
North Miami Beach, FL 33162 U.S.A.

**Drug Facts**  
**Active ingredient (in each caplet)**  
 Loperamide HCl 2 mg  
**Purpose**  
 Anti-diarrheal  
**Use**  
 controls symptoms of diarrhea, including Traveler's Diarrhea

**KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**



Compare to the active ingredient in Imodium® A-D\*

NDC 80513-375-08

# ANTI-DIARRHEAL

Loperamide HCl Tablets, 2 mg  
 Anti-Diarrheal

Controls the symptoms of diarrhea

24 CAPLETS



Actual Size

- To open, tear at perforations and remove a section.
- Use 3/4 to cut through plastic for caplet.

\*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Imodium® A-D. 50844 REV0325A37508  
 Distributed by: **ADVANCED RX LLC**  
 1942 NE 163rd St  
 North Miami Beach, FL 33162 U.S.A.

No print/No varnish  
 Lot & Exp date

TAMPER EVIDENT: DO NOT USE IF PACKAGES IS OPENED OR IF BUSTER UNITS IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



**Drug Facts (continued)**  
 ■ 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

B-1365-375-08  
 REV0325A37508

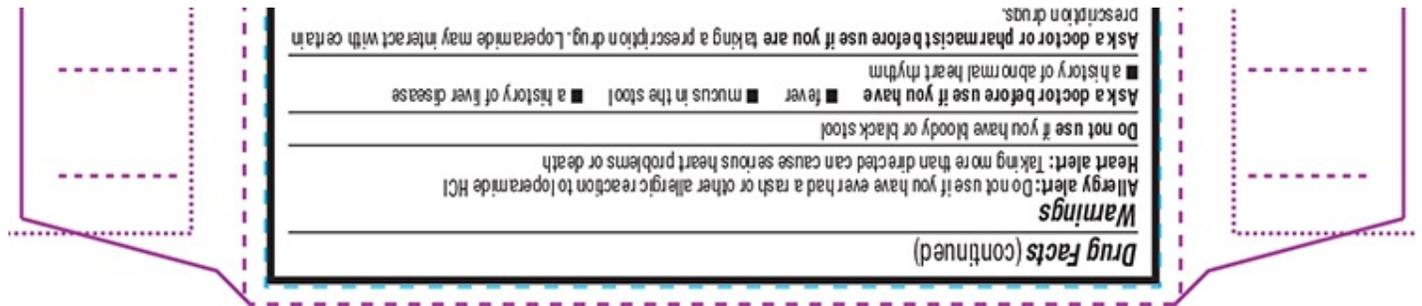
**Other information**  
 ■ each caplet contains: calcium 15 mg  
 ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTER IS TORN OR BROKEN

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

**Stop use and ask a doctor if**  
 ■ symptoms get worse ■ diarrhea lasts for more than 2 days  
 ■ you get abdominal swelling or bloating. 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.

When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.



## Puregen 44-375

### ANTI-DIARRHEAL

loperamide hcl tablet

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80513-375
<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:80513-375-08	4 in 1 CARTON	01/03/2025	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination		

Product			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076497	01/03/2025	

**Labeler -** Advanced Rx LLC (042795108)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(80513-375) , pack(80513-375)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(80513-375)

Revised: 11/2025

Advanced Rx LLC