

**ANTI DIARRHEAL- loperamide hcl tablet**  
**Bedrock Brands, LLC**

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**Di-Gel 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.

**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

**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 (1-800-222-1222) 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 under 6 years (up to 47 lbs)	ask a doctor

**Other information**

- do not use if carton or blister unit is open or torn
- 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, dicalcium phosphate dihydrate, FD&C blue #1 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel

**Questions or comments?**

**Call 1-855-GODIGEL (1-855-463-4435)**

**Principal Display Panel**

**di•gel™**

Anti-Diarrheal

**Anti-Diarrheal**

regular strength

Loperamide HCl 2 mg

*CONTROLS THE SYMPTOMS OF DIARRHEA*

bloating & pressure cramps

**48** Caplets

actual size

**di•gel™**

Distributed by: di•gel Health Products, LLC.  
323 W. Camden Street, Baltimore, MD 21201  
1-855-GODIGEL • www.godigel.com

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

**Drug Facts (continued)**

**Other information**

- do not use if carton or blister unit is open or torn
- store between 20°-25°C (68°-77°F)
- see end flap for expiration date and lot number

**Inactive ingredients** cam starch, D&C yellow #10 aluminum lake, disodium phosphate dry hydrate, FD&C blue #1 Brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel

**Questions or comments?** Call 1-855-600ISEL (1-855-463-4435)

**Drug Facts**

**Active ingredient (in each caplet)** Loperamide HCl 2 mg, ... Anti-diarrheal

**Purpose** ... Anti-diarrheal

**Use** controls symptoms of diarrhea, including travelers' diarrhea

**Warnings** Do not use if you have had a rash or other allergic reaction to loperamide HCl. **Allergy alert:** Do not use if you have 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:** ■ a fever ■ a 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

**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 (1-800-222-1222) 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 17 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 6-11 years (60-65 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 5-6 years (45-59 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 5 years (up to 47 lbs)	ask a doctor



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



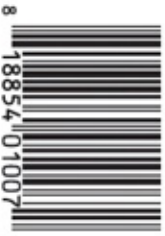
2. Use scissors to cut through plastic for caplet.



**di-gel**

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**PLEASE RECYCLE**



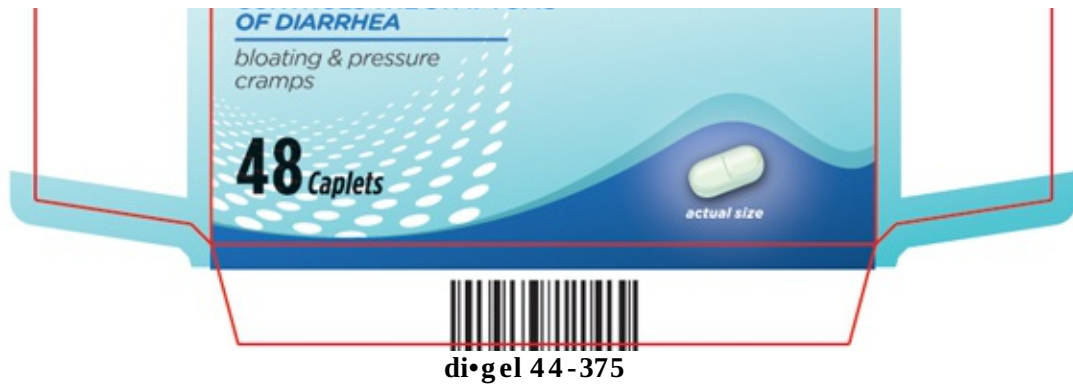
**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**



8-0775-375-22  
ORIG121237522





## ANTI DIARRHEAL

loperamide hcl tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76000-375
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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:76000-375-22	8 in 1 CARTON	05/03/2005	07/08/2019
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	05/03/2005	07/08/2019

**Labeler** - Bedrock Brands, LLC (829056162)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(76000-375)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(76000-375)

Revised: 8/2016

Bedrock Brands, LLC