# ANTI DIARRHEAL- loperamide hydrochloride capsule 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 reactions to loperamide HCl.

#### Do not use

if you have bloody or black stool.

#### Ask a doctor before use if you have

- high 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 buldging. 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 chat. If possible, use weight to dose; otherwise, use age.

	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
	1 caplet after first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
	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 safety seal is broken or missing
- 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 LOPERAMIDE HCl 2 mg

regular strength

CONTROLS THE SYMPTOMS OF DIARRHEA bloating & pressure cramps

48 Caplets

di•gel<sup>TM</sup>

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

#### Questions or comments? Cal 1-855-60016EL (1-855-463-4435)

17 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel Inactive ingredients com starch, D&C yellow #10 aluminum late,, dicalcium phosphate ditydrate, FD&C blue

> see eud tjeb tor expiration date and lot number a do not use il carton or blister unit is open or torn Other information

> > Dung Facts (continued)



To open, tear
 at perforations and
 remove a section.

Use scissors to cut through plastic for caplet.

regular

48 Caplets

Anti-Diarrheal

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

■ find right dose on chart. If possible, use weight to dose; otherwise, use age. m quink blenty of clear fluids to help prevent dehydration caused by diarrhea Directions

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

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Ask a doctor before use if you have 🔳 a fever 🔳 mucus in the stool 🔳 a history of liver disease

Do not use if you have bloody or black stool.

Altergy stort. Do not use if you have ever had a rash or other allergic reaction to loperamide HCH. Marnings

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Active ingredient (in each caplet)

Drug Facts

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Distributed by: digel Health Products, 323 W. Carnden Street, Battimore, MD 1-855-GCDIGEL • www.godgel.com

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Purpose

di-gel

Anti-**Diarrheal** 

CONTROLS THE SYMPTOMS OF DIARRHEA

regular strength

regular strength

48 Caplets

B-0775-375-22 0RG121237522

# di-ge

Anti-**Diarrheal** 

Loperamide HCI 2 mg CONTROLS THE SYMPTOMS



# **ANTI DIARRHEAL**

loperamide hcl capsule

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Pro	duct	Intori	mation
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 Product Type
 HUMAN OTC DRUG LABEL
 Item Code (Source)
 NDC:76000-375

 Route of Administration
 ORAL
 DEA Schedule

# **Active Ingredient/Active Moiety**

 Ingredient Name
 Basis of Strength
 Strength

 LOPERAMIDE HYDROCHLORIDE (LOPERAMIDE)
 LOPERAMIDE HYDROCHLORIDE
 2 mg

#### **Inactive Ingredients**

Ingredient Name	Strength
MAGNESIUM STEARATE	
CELLULO SE, MICRO CRYSTALLINE	

### **Product Characteristics**

Color	BLUE	Score	no score
Shape	CAPSULE	Size	10 mm
Flavor		Imprint Code	44;375
Contains			

#### **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76000-375-22	1 in 1 CARTON		
1	48 in 1 BLISTER PACK		

Mar	keting	Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076497	05/03/2005	

# 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: 7/2013 Bedrock Brands, LLC