

ANTI-DIARRHEAL- loperamide hcl tablet
GREENBRIER INTERNATIONAL, INC.

Assured 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 (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 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

ASSURED™

**COMPARE TO ACTIVE INGREDIENT OF
IMODIUM® A-D***

**ANTI-
DIARRHEAL**

• **Loperamide HCl Tablets, 2 mg**
Anti-diarrheal

Controls the symptoms of diarrhea

Actual Size

12 caplets

**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.

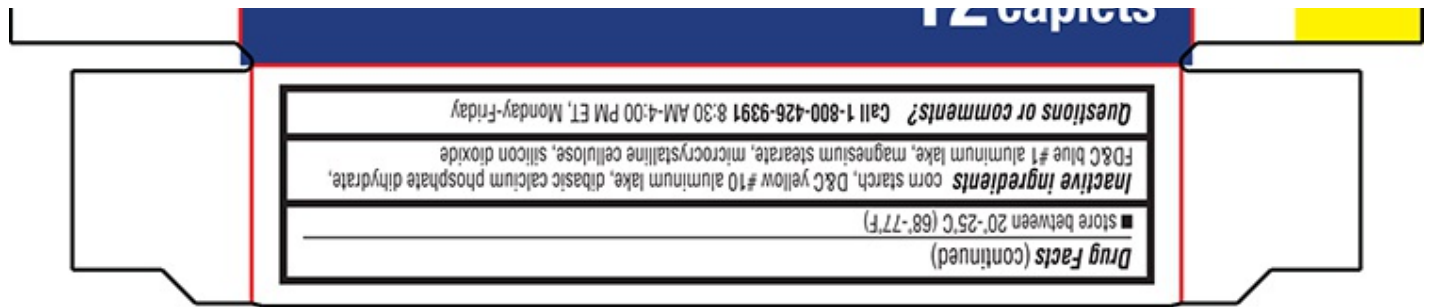
2. Use □ to cut
through plastic
for caplet.

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

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ITEM# 10682

Distributed by: **Greenbrier International, Inc.**
Chesapeake, VA 23320 USA



Assured 44-375

ANTI-DIARRHEAL

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0375
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
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DE6)	
FD&C BLUE NO. 1--ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6B0)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	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:33992-0375-2	2 in 1 CARTON	05/03/2005	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:33992-0375-8	4 in 1 CARTON	05/03/2005	09/30/2021
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

3	NDC:33992-0375-4	1 in 1 CARTON	05/03/2005	07/08/2018
3		96 in 1 BOTTLE; 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	

Labeler - GREENBRIER INTERNATIONAL, INC. (610322518)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(33992-0375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(33992-0375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(33992-0375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(33992-0375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(33992-0375)

Revised: 3/2020

GREENBRIER INTERNATIONAL, INC.