

**ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled
ASSURED / DOLLAR TREE (Greenbrier International, Inc.)**

Drug Facts

Active ingredient (in each capsule)

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
- in children under 12 years of age

Ask a doctor before use if you have

- 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 right away.

Directions

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- **not for use in children under 12 years of age**
- adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours

Other information

- store at 20°-25°C (68°-77°F). Protect from light
- avoid excessive heat above 40°C (104°F)
- do not use if carton or blister unit is open or torn
- see side panel for lot number and expiration date

Inactive ingredients

butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water.

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

COMPARE TO ACTIVE INGREDIENT OF IMODIUM® A-D*

ANTI-DIARRHEAL

LOPERAMIDE HCl SOFT GELATIN CAPSULES, 2 MG

Anti-diarrheal

Suitable for adults and children 12 years and over

Controls the symptoms of diarrhea

softgels**

**each liquid-filled capsule

contains 2 mg loperamide HCl

*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY

GREENBRIER INTERNATIONAL, INC.

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Product Label

*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

<p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	<p>◀ signs of a serious condition. ■ you get abdominal swelling or bulging. These may be ■ diarrhea lasts for more than 2 days ■ symptoms get worse Stop use and ask a doctor if</p>
<p>Inactive ingredients butylated hydroxyanisole, edible ink, FD&C blue #1, gelatin, glycerin, glyceryl caprylate, polyoxy 40 hydrogenated castor oil, purified water</p>	<p>When using this product tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.</p>
<p>Other information ■ store at 20°-25°C (68°-77°F). Protect from light. ■ avoid excessive heat above 40°C (104°F) ■ do not use if carton or blister unit is open or torn ■ see side panel for lot number and expiration date</p>	<p>Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease Ask a doctor or pharmacist before use if you are taking antibiotics.</p>
<p>Directions ■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea ■ not for use in children under 12 years of age ■ adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours</p>	<p>Do not use ■ if you have bloody or black stool ■ in children under 12 years of age 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.</p>
<p>Drug Facts (continued) 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.</p>	<p>Drug Facts Loperamide HCl 2 mg.....Anti-diarrheal Active ingredient (in each capsule) Loperamide HCl 2 mg.....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.</p>

ANTI-DIARRHEAL

• Loperamide HCl Soft Gelatin Capsules, 2 mg





COMPARE TO ACTIVE INGREDIENT OF
IMODIUM® A-D*

NDC 33992-0820-2

ANTI-DIARRHEAL

TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.
 SEE WARNINGS AND PRODUCT INFORMATION.

• **Loperamide HCl Soft Gelatin Capsules, 2 mg**
Anti-diarrheal

**Suitable for adults and children
12 years and over**

Controls the symptoms of diarrhea



Actual Size

12 softgels**

**each liquid-filled capsule
contains 2 mg Loperamide HCl

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND
KEEP OUTER CARTON FOR COMPLETE

Lot No.:
Exp. Date:

DISTRIBUTED BY
GREENBRIER INTERNATIONAL, INC.
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

REV # 9/16
PLD-C45J FC005428



ASSURED Anti-Diarrheal

ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0820
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
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	LP2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0820-2	12 in 1 CARTON	09/30/2018	12/31/2023
1		1 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
NDA	NDA021855	09/30/2018	12/31/2023

Labeler - ASSURED / DOLLAR TREE (Greenbrier International, Inc.) (610322518)

Revised: 10/2021

ASSURED / DOLLAR TREE (Greenbrier International, Inc.)