

**ANTI-DIARRHEAL- loperamide hydrochloride tablet**  
**SDA Laboratories, Inc.**

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**ANTI-DIARRHEAL**

**Loperamide Hydrochloride Caplets, 2 mg**

***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 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 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.

<b>adults and children 12 years and over</b>	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
<b>children 9-11 years (60-95 lbs)</b>	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
<b>children 6-8 years (48-59 lbs)</b>	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
<b>children 2-5 years (34-47 lbs)</b>	ask a doctor
<b>children under 2 years (up to 33 lbs)</b>	do not use

**Other information**

- **THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE: USE ONLY IF BLISTERS ARE INTACT**
- do not use if blister unit is torn or open
- store at 20°-25°C (68°-77°F)
- KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
- 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 brilliant blue, magnesium stearate, microcrystalline cellulose, silica gel

**Questions?**

call toll-free 1-866-933-6337

Distributed by:

**SDA Laboratories, Inc.**

Greenwich, CT 06830

Made in the USA

***Principal Display Panel***

**NDC 66424-725-24**

Compare to the active ingredient in **Imodium<sup>®</sup> A-D †**

**Anti-Diarrheal**

**Loperamide Hydrochloride Caplets, 2 mg**

Controls Symptoms of Diarrhea

**24 Caplets**

†This product is not manufactured or distributed by the owner of the registered trademark Imodium<sup>®</sup> A-D.

**Drug Facts (continued)**

**Other information** ■ do not use if blister unit is torn or open ■ store at 20°-25°C (68°-77°F)

**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?** call toll-free 1-866-933-6337

24 Caplets

CONTROLS SYMPTOMS OF DIARRHEA

ORIGINAL PRESCRIPTION STRENGTH

Each caplet contains Loperamide HCl, 2 mg

LOPERAMIDE HYDROCHLORIDE CAPLETS, 2 mg

# ANTI-DIARRHEAL

NDC 66424-725-24



Compare to the active ingredient in Imodium® A-D†



†This product is not manufactured or distributed by the owner of the registered trademark Imodium® A-D

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

07811-024-101-0

ANTI-DIARRHEAL LOPERAMIDE HYDROCHLORIDE CAPLETS, 2 mg 24 Caplets



Made in the USA

Distributed by:  
SDA Laboratories, Inc.  
Greenwich, CT 06830

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

**Drug Facts**

**Active ingredient (in each caplet)**

Loperamide HCl 2 mg

**Purpose**

Anti-diarrheal

**Use** Controls symptoms of diarrhea, including Travelers' Diarrhea

**Warnings**

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**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 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 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.

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## ANTI-DIARRHEAL

loperamide hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66424-725
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<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	<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

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66424-725-24	4 in 1 CARTON	02/01/2024	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA076497	02/01/2024	

**Labeler** - SDA Laboratories, Inc. (948067889)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(66424-725) , pack(66424-725)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(66424-725)

Revised: 4/2024

SDA Laboratories, Inc.