

ANTI-DIARRHEAL- loperamide hcl tablet
WinCo Foods, LLC

Winco 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 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

- store between 20°-25°C (68°-77°F)
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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 1-800-824-1706 Monday-Friday 9am - 4pm MST

Principal Display Panel

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

WinCo®
FOODS

Anti-Diarrheal

LOPERAMIDE HCl TABLETS, 2 mg/
ANTI-DIARRHEAL
Controls the Symptoms of Diarrhea

12

Caplets*

*Capsule-Shaped Tablets

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

DISTRIBUTED BY:

WINCO FOODS, LLC,
BOISE, ID 83704

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

2. Use ✂ to cut
through plastic
for caplet.

100% SATISFACTION GUARANTEE

Comments & Questions?

800-824-1706 • www.wincofoods.com

†This product is not manufactured or distributed
by JOHNSON & JOHNSON CORPORATION,
distributor of IMODIUM® A-D.
50844 REV0619B37502

Drug Facts (continued)
 ■ 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
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Drug Facts (continued)
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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 ■ 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 right away.
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Use controls symptoms of diarrhea, including Travelers' Diarrhea

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

WinCo FOODS

Anti-Diarrheal

LOPERAMIDE HCl TABLETS, 2 mg/
 ANTI-DIARRHEAL

Controls the Symptoms of Diarrhea

12



2. Use $\frac{3}{8}$ " to cut through plastic for caplet.



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

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100% SATISFACTION GUARANTEE
 Comments & Questions?
 800-824-1706 · www.wincofoods.com

DISTRIBUTED BY:
 WINCO FOODS, LLC,
 BOISE, ID 83704

B-2150-375-02
 REV0619B37502

No Print/No varnish
 Lot & Exp date

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Winco 44-375

ANTI-DIARRHEAL

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-335
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
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
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:67091-335-18	2 in 1 CARTON	02/08/2019	
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	02/08/2019	

Labeler - WinCo Foods, LLC (056098817)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(67091-335) , pack(67091-335)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(67091-335)

Revised: 3/2024

WinCo Foods, LLC