

LEADER ANTI DIARRHEAL- loperamide hcl tablet, film coated
Cardinal Health 110, LLC. dba Leader

Cardinal Health Anti-Diarrheal Drug Facts

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

- 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 (1-800-222-1222).

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 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

Other information

- store at 20°-25°C (68°-77°F)
- see end panel for lot number and expiration date

Inactive ingredients

anhydrous lactose, carnauba wax, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

Questions or comments?

1-800-719-9260

Principal Display Panel

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg Anti-Diarrheal

Controls the Symptoms of Diarrhea

COMPARE TO IMODIUM® A-D

active ingredient

12 CAPLETS*

*Capsule-Shaped Tablets

Actual Size

100% Money Back Guarantee

SEE NEW WARNINGS

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

00014/13741

22453 E9 C10

OPEN OTHER END

LEADERTM

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg
Anti-Diarrheal

LEADERTM

Anti-Diarrheal

NDC 70000-0225-2

Drug Facts

Active ingredient (in each caplet)
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. 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, or if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.

When using this product, dizziness, 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 bloating. These may be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use.

Other information
Store at 20°-25°C (68°-77°F). See end panel for lot number and expiration date.

Drug Facts (continued)

Purpose
Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away (1-800-222-1222).

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.

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Children 2-5 years (34 to 47 lbs): ask a doctor.

Children under 2 years (up to 33 lbs): do not use.

Drug Facts (continued)

Inactive ingredients anhydrous lactose, carnauba wax, D & C yellow no. 10 aluminum lake, FD & C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch.

Drug Facts (continued)
Questions or comments?
1-800-719-9260

This product is manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Modium[®] A-D.



REV. 11/19



Return to place of purchase.

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DUBLIN, OHIO 43017
www.jhleader.com 1-800-200-6313

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LEADER ANTI DIARRHEAL

loperamide hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0225
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	GREEN	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	L2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0225-1	24 in 1 CARTON	01/17/2017	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0225-2	12 in 1 CARTON	02/02/2020	
2		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
ANDA	ANDA075232	01/17/2017	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 6/2021

Cardinal Health 110, LLC. dba Leader