

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

24 CAPLETS*

*Capsule-Shaped Tablets

Actual Size

100% Money Back Guarantee

SEE NEW WARNINGS

22462 E9 C3

WATERMELON

OPEN OTHER END

LEADER[?]

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg
Anti-Diarrheal

Controls the Symptoms
of Diarrhea

LEADER[?]

NDC 70000-0580-1

Anti-Diarrheal

Loperamide Hydrochloride Tablets, 2 mg
Anti-Diarrheal

Drug Facts (continued)

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 ■ find right dose on chart. If possible, use weight to dose; otherwise, use age.

Warnings
 ■ **Heart alert:** Taking more than directed can cause serious heart problems or death
 ■ **Don't use if you have** bloody or black stool
 ■ **Ask a doctor before use if you have**
 ■ fever
 ■ muscle in the stool
 ■ a history of liver disease
 ■ a history of abnormal heart rhythm

Use controls symptoms of diarrhea, including Travelers' Diarrhea

Active ingredient (in each caplet) Loperamide HCl 2 mg.....Anti-diarrheal

Purpose

Drug Facts

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 bloating.

These may be signs of a serious condition. If you get abdominal swelling or bloating, professional before use.

Drug Facts (continued)
Inactive ingredients anhydrous lactose, camphor, FD&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

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Drug Facts (continued)

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100% Money Back Guarantee
 Return of the product in original packaging. See www.leaderpharm.com for details.

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 ■ see end panel for lot number and expiration date

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CONVENIENT RE-CLOSING TAB

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN
 **This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Imodium® A-D.





LEADER ANTI DIARRHEAL

loperamide hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0589
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:70000-0589-1	24 in 1 CARTON	10/07/2021	
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
ANDA	ANDA075232	10/07/2021	

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

Revised: 10/2021

Cardinal Health 110, LLC. dba Leader