

ANTI-DIARRHEAL LOPERAMIDE HCL, 2 MG CAPLETS- loperamide hcl tablet
SDA Laboratories, Inc.

SDA LABORATORIES - ANTI-DIARRHEAL LOPERAMIDE HYDROCHLORIDE, 2 mg
CAPLETS

Drug Facts

Active ingredient (in each caplet)

Loperamide HCl 2 mg

Purpose

Anti-diarrheal

Use

controls symptoms of diarrhea, including Traveler's 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

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 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **drink plenty of clear liquids to help prevent dehydration caused by diarrhea**

- find the right dose on the 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 under 6 years (up to 47 lbs)	ask a doctor

Other information

- store between 20° and 25°C (68° and 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 **1-800-687-0176**

Mon - Fri 8 am to 4 pm

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

ORIGINAL PRESCRIPTION STRENGTH

CONTROLS SYMPTOMS OF DIARRHEA

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

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

L.Rev. 08/18

Distributed by:

SDA Laboratories, Inc.

Greenwich, CT 06830



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LABORATORIES

NDC 66424-735-96

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

ANTI-DIARRHEAL

LOPERAMIDE HYDROCHLORIDE CAPLETS, 2 mg

Each caplet contains Loperamide HCl, 2 mg

ORIGINAL PRESCRIPTION STRENGTH

CONTROLS SYMPTOMS OF DIARRHEA

96 Caplets



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LABORATORIES

NDC 66424-735-02

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

ANTI-DIARRHEAL

LOPERAMIDE HYDROCHLORIDE CAPLETS, 2 mg

Each caplet contains Loperamide HCl, 2 mg

ORIGINAL PRESCRIPTION STRENGTH

CONTROLS SYMPTOMS OF DIARRHEA

200 Caplets

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

<i>Active ingredient</i> <i>(in each caplet)</i>	<i>Purpose</i>
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Loperamide HCl 2 mg.....	Anti-diarrheal
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Use controls symptoms of diarrhea, including Traveler's 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 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.

LIFT HERE

■ PEEL FOR DIRECTIONS G7811-096-101-2

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 (1-800-222-1222) right away.

Directions ■ drink plenty of clear liquids to help prevent dehydration caused by diarrhea
■ find the 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 between 20° and 25°C (68° and 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 1-800-687-0176
Mon – Fri 8 am to 4 pm

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L.Rev. 09/18

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ANTI-DIARRHEAL LOPERAMIDE HCL, 2 MG CAPLETS

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66424-735
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
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Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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:66424-735-02	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2018	
2	NDC:66424-735-96	96 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076497	09/01/2018	

Labeler - SDA Laboratories, Inc. (948067889)