

ANTI-DIARRHEAL- loperamide hcl tablet
Better Living Brands, LLC

Signature Care 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 (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.

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

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Principal Display Panel

Signature[™]

care

Quality

Guaranteed

COMPARE TO Imodium® A-D active ingredient*

NDC 21130-375-08

Anti-Diarrheal

LOPERAMIDE HCl 2 mg

Anti-Diarrheal

Controls the symptoms
of diarrhea

Actual Size

24 CAPLETS

*This product is not manufactured or distributed by Johnson & Johnson Corporation, distributors of Imodium[®] A-D.

50844 REV0619N37508

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

DISTRIBUTED BY

BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

1-888-723-3929

www.betterlivingbrandsLLC.com

OUR PROMISE

QUALITY & SATISFACTION

100% GUARANTEED

OR YOUR MONEY BACK.

Drug Facts
Active ingredient (in each caplet)
 Loperamide HCl 2 mg
Purpose
 Anti-diarrheal
Use
 controls symptoms of diarrhea, including Traveler's Diarrhea
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION



Quality
Guaranteed

COMPARE TO
Imodium® A-D
 active ingredient*
 NDC 21130-375-08



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for more
information

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Anti-Diarrheal

LOPERAMIDE HCl 2 mg

Anti-Diarrheal

Controls the symptoms
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Actual Size



24 CAPLETS

1. To open, tear at perforations and remove a section.
2. Use $\frac{1}{2}$ to cut through plastic for caplet.



COMT IMO



S1714

RD 19272

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B-1817-375-08-S
 REV0619N37508

Other information	
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Inactive ingredients	
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Questions or comments?	
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Signature Care 44-375

ANTI-DIARRHEAL

loperamide hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-375
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
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:21130-375-08	4 in 1 CARTON	05/03/2005	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:21130-375-22	1 in 1 CARTON	05/03/2005	05/01/2022
2		48 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:21130-375-46	1 in 1 CARTON	05/03/2005	05/01/2022
3		96 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076497	05/03/2005	

Labeler - Better Living Brands, LLC (009137209)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(21130-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(21130-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(21130-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(21130-375)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(21130-375)

Revised: 5/2020

Better Living Brands, LLC