

ANTI-DIARRHEAL- loperamide hydrochloride tablet
Advanced Rx LLC

ANTI-DIARRHEAL

Loperamide Hydrochloride Caplets, 2 mg

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 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 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 liquid 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

- do not use if seal around caplet is broken or damaged
- store between 20° and 25°C (68° and 77°F)
- **KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**
- **THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TEMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.**

Inactive ingredients

corn starch, D&C yellow#10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue#1 brilliant blue lake, magnesium stearate, microcrystalline cellulose, silica gel.

Questions?

call toll-free **1-800-630-8895**

Distributed by:

ADVANCED RX LLC,

1942 NE 163rd St,
North Miami Beach,
FL 33162 U.S.A.

Principal Display Panel

NDC 80513-401-24

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

Anti-Diarrheal

Loperamide Hydrochloride Caplets, 2 mg

Controls Symptoms of Diarrhea

Easy To Swallow

24 CAPLETS

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

Drug Facts (continued)

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 1-800-630-8895

Distributed by: **ADVANCED RX LLC**, 1942 NE 163rd St North Miami Beach, FL 33162 U.S.A.

24 CAPLETS
Easy To Swallow



FAST ACTING



Controls the symptoms of diarrhea

Loperamide HCl Caplets, 2 mg

ANTI-DIARRHEAL

NDC 80513-401-24



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



ANTI-DIARRHEAL

Loperamide HCl Caplets, 2 mg

Loperamide HCl Caplets, 2 mg

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 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 liquids 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 ■ do not use if seal around caplet is broken or damaged ■ store between 20° and 25°C (68° and 77°F) **continued**

This product is not manufactured or distributed by the owner of the registered trademark Imodium® A-D
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
 THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TEMPER EVIDENT PACKAGE. USE ONLY IF BUSTERS ARE INTACT.

3 80513 00103 0
 07811-024-106-0

loperamide hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-401
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:80513-401-24	4 in 1 CARTON	08/11/2024	
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	01/01/2024	

Labeler - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	manufacture(80513-401) , label(80513-401) , pack(80513-401)

Revised: 8/2024

Advanced Rx LLC