# ANTI DIARRHEAL- loperamide hel tablet Chain Drug Marketing Association, Inc.

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**Quality Choice 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 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.

	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
r illicii eli N-A Veals	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

**QC**® QUALITY

#### CHOICE

NDC 83324-064-24

\*Compare to the Active Ingredient in IMODIUM® A-D

#### **Anti-Diarrheal**

Loperamide HCl Tablets, 2 mg Anti-Diarrheal Controls the Symptoms of Diarrhea

Actual Size

**24** Caplets

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

\*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark IMODIUM® A-D. 50844 REV0619B37508

SATISFACTION
100%
QC
GUARANTEED

Distributed by CDMA, Inc. Novi, MI 48375 www.qualitychoice.com Questions: 800-935-2362

USB controls symptoms of diarrhea, including Travelers' Diarrhea Loperamide HCI 2 mg Anti-diambeal Purpose Active ingredient (in each caplet) Drug Facts KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION NDC 83324-064-24 \*Compare to the Active Ingredient in IMODIUM® A-D **CHOICE** perforations and **Anti-Diarrheal** \*This product is not manufactured or distributed by Kervue Inc., owner of the registered trademark IMODIUM® A.D. 50844 REV0619837508 Loperamide HCI Tablets, 2 mg **Anti-Diarrheal** Distributed by CDMA, **Controls the Symptoms of Diarrhea** Actual Size



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

B-0220-375-08-R REV0619B37508

Vo Print / No Varnish Lot no. & Exp. date

355 15

"9964"

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

FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide Inactive ingredients corn starch, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate,

> see end flap for expiration date and lot number ■ store between 20"-25"C (68"-77"F)

> > nund racts (continued)

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN Other information

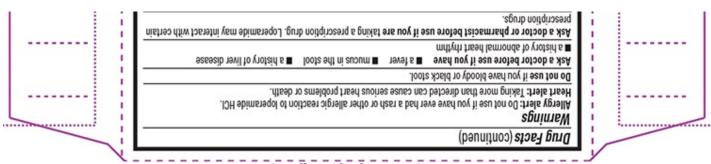
esu fon ob	children under 2 years (up to 33 lbs)
ssk a doctor	children 2-5 years (34-47 lbs)
1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours	children 6-8 years (48-59 lbs)
1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours	children 9-11 years (60-95 lbs)
2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours	adults and children 12 years and over

■ find right dose on chart. If possible, use weight to dose; otherwise, use age. drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use.

> you get abdominal swelling or bulging. These may be signs of a serious condition. Stop use and ask a doctor if symptoms get worse diarrhea lasts for more than 2 days

When using this product, tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating



#### **Quality Choice 44-375**

#### ANTI DIARRHEAL

loperamide hcl tablet

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:83324-064

**Route of Administration** ORAL

#### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE -LOPERAMIDE 2 mg

UNII:6X9OC3H4II)

**HYDROCHLORIDE** 

## **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:83324-064-	4 in 1 CARTON	06/17/2024	
1	6 in 1 BLISTER PACK; Type 0: Not a Combination		

ANDA	ANDA076497	06/17/2024		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing Information				
- F	Product			

## Labeler - Chain Drug Marketing Association, Inc. (011920774)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	manufacture(83324-064) , pack(83324-064)	

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		117025878	manufacture(83324-064)	

Revised: 6/2024 Chain Drug Marketing Association, Inc.