# WELMATE ANTI DIARRHEAL LOPERAMIDE HCL- loperamide hydrochloride tablet YYBA CORP

-----

### WELMATE Anti-Diarrheal (Loperamide HCl) Caplets

## **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 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 2 caplets after the first loose stool; 1 caplet after each subsequent years and over loose stool; but no more than 4 caplets in 24 hours **children 9-11 years (60-** 1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours 95 lbs) children 6-8 years (48-1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours 59 lbs) children 2-5 years (34 ask a doctor to 47 lbs) children under 2 years do not use (up to 33 lbs)

#### Other information

- do not use if blister unit is torn or open
- store at 20° 25°C (68° 77°F)

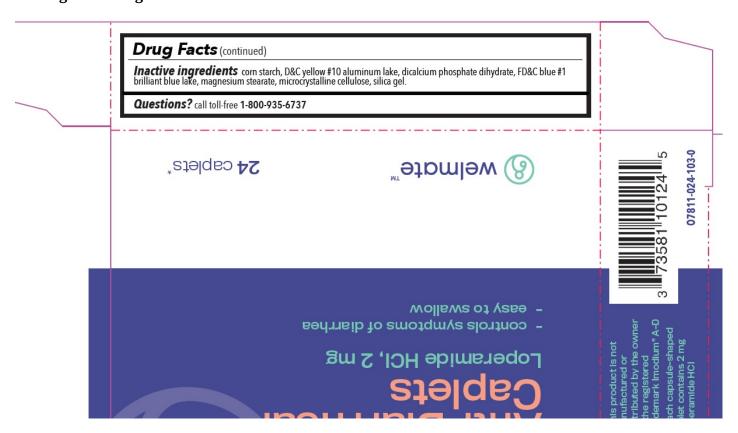
## **Inactive ingredients**

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 1-800-935-6737

#### **Package Labeling:**



ma distribution of the strain of the strain

PRODUCT INFORMATION.

Compare to the active ingredient in Imodium A-D<sup>†</sup>

NDC \3281-101-54

THIS PRODUCT IS PACKAGED IN A
CHILD-RESISTANT AND TAMPER
EVIDENT PACKAGE. USE ONLY IF
BLISTERS ARE INTACT.
KEEP OUTER CARTON POR
COMPLETE WARNINGS AND

## Anti-Diarrheal Caplets\* Loperamide HCl, 2 mg | 24 caplets\*

& welmate"





**(1)** 

Why pay more? wellspringmeds.com

Distributed by:
Wellspring
Airmont, NY 10952

Active ingredient (in each caplet)	13 <u>25</u> 4764999
Loperamide HCl 2 mg	Purpose Anti-diarrheal
Use Controls symptoms of diarrhea, including Travelers' Diarrhea	Anti diannicai

#### 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 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** • do not use if blister unit is torn or open • store at 20° - 25°C (68° - 77°F)

#### WELMATE ANTI DIARRHEAL LOPERAMIDE HCL

loperamide hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73581-101
Route of Administration	ORAL		

	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
- 1			

ı	LUPERAMINE HIDRUCHLURIDE (UNII: //IISSSSSC) (LUPERAMINE -	LUPEKAMIDE	2 mg
	UNII:6 X9 OC3H4II)	HYDROCHLORIDE	2 mg

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)			
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			

Product Characteristics				
Color	green (Light green)	Score	2 pieces	
Shape	OVAL	Size	8 mm	
Flavor		Imprint Code	44;375	
Contains				

1	Packaging			
#	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:73581-101-24	4 in 1 CARTON	08/22/2020	
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	08/22/2020	

## **Labeler -** YYBA CORP (006339772)

Revised: 8/2020 YYBA CORP