

**ANTI DIARRHEAL- loperamide hydrochloride tablet, film coated**  
**Publix Super Markets Inc**

-----  
**Publix Super Markets, Inc. 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 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 (1-800-222-1222).

## 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

- store at 68°-77°F (20°-25°C)
- see end panel for lot number and expiration date

## Inactive ingredients

anhydrous lactose, carnauba wax, D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch

## Principal Display Panel

LOPERAMIDE HYDROCHLORIDE TABLETS, 2 mg

antidiarrheal

ACTUAL SIZE

Controls the symptoms of diarrhea

Anti-diarrheal

12 CAPLETS\*

\*CAPSULE-SHAPED TABLETS

Compare to Imodium® A-D active ingredient

SEE NEW WARNINGS

22453 63 C8

OPEN OTHER END

000005/04173

**LOPERAMIDE HYDROCHLORIDE TABLETS, 2 mg**  
**antidiarrheal**

**LOPERAMIDE HYDROCHLORIDE TABLETS, 2 mg**  
**antidiarrheal**

NDC 56062-224-53



**Drug Facts**  
**Active ingredient** (in each caplet) Loperamide HCl 2 mg.....Anti-diarrheal  
**Purpose** 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:  
■ ever ■ 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 treadness, 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 bloating.  
These may be signs of a serious condition. If pregnant or breastfeeding, ask a health professional before use.

**Drug Facts** (continued)  
**Inactive ingredients** D&C yellow no. 10 aluminum lake, FD&C blue no. 1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch.  
PUBLIX SUPER MARKETS, INC.  
3300 PUBLIX CORPORATE PARKWAY  
LAKELAND, FL 33811  
1-888-267-3037 publix.com  
PUBLIX GUARANTEE: COMPLETE SATISFACTION OR YOUR MONEY BACK

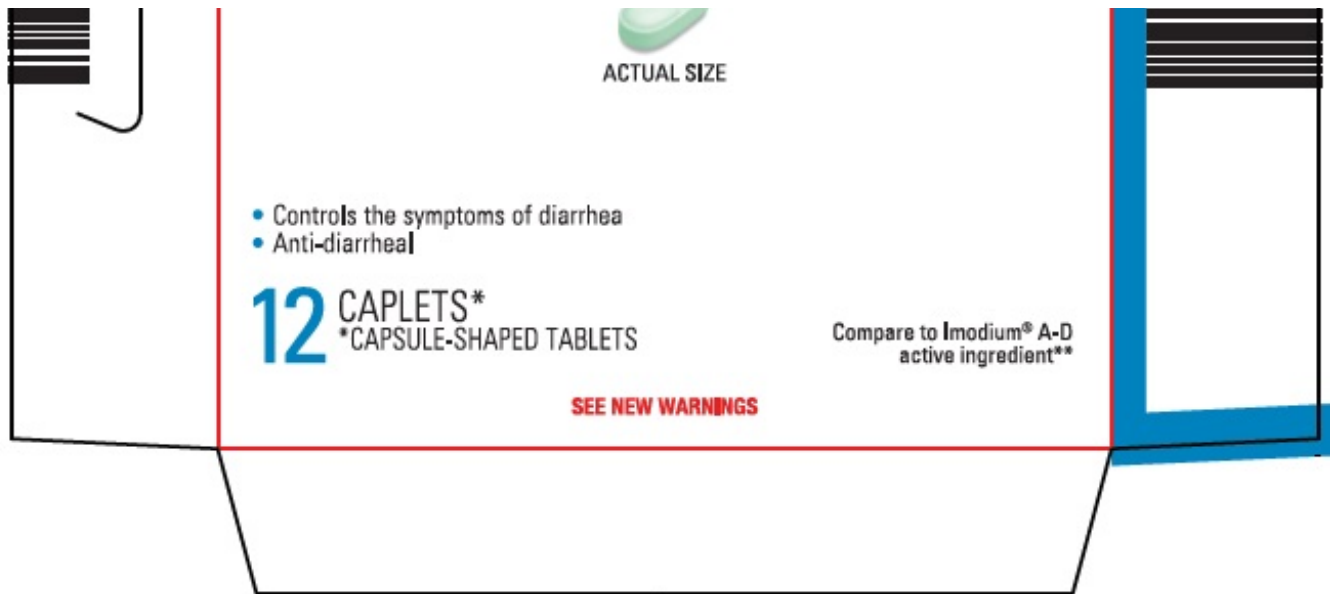
**Directions**  
Keep out of reach of children in case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).  
2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours and over  
children 9-11 years 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 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 ask a doctor  
children under 2 years do not use (up to 3 lbs)

**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:  
■ ever ■ 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 treadness, 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 bloating.  
These may be signs of a serious condition. If pregnant or breastfeeding, ask a health professional before use.

**Other information**  
■ store at 68°-77°F (20°-25°C)  
■ see end panel for lot number and expiration date



**DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN**  
\*\*This product is not manufactured or distributed by the owner of the registered trademark Imodium®.



## ANTI DIARRHEAL

loperamide hydrochloride tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-224
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	

### Product Characteristics

Color	GREEN	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	L2
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-224-53	12 in 1 CARTON	03/19/2003	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:56062-224-62	24 in 1 CARTON	03/25/2003	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:56062-224-80	1 in 1 CARTON	01/13/2005	
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	ANDA075232	03/19/2003	

**Labeler** - Publix Super Markets Inc (006922009)

Revised: 9/2019

Publix Super Markets Inc