#### LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet WALMART INC.

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## **Drug Facts**

#### Active ingredients (in each caplet)

Loperamide HCl USP 2 mg Simethicone USP 125 mg

## Purposes

Anti-diarrheal Anti-gas

#### Uses

relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

#### Warnings

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCI

Heart alert: Taking more than directed can cause serious heart problems or death

#### Do not use

- if you have bloody or black stool
- if you have difficulty swallowing

## 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.
- you have difficulty swallowing the caplet

## 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
- take only on an empty stomach (1 hour before or 2 hours after a meal)
- take with a full (8 oz.) glass of water
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and 2 caplets after the first loose stool; 1 over caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9 to 11 years (60 to 951 caplet after the first loose stool; $\frac{1}{2}$
lbs) caplet
after each subsequent loose stool; but
no more than 3 caplets in 24 hours
children 6 to 8 years (48 to 59 lbs) 1 caplet after the first loose stool; $\frac{1}{2}$
caplet after each subsequent loose
stool; but no more than 2 caplets in 24
hours
children 2 to 5 years (34 to 47 lbs) ask a doctor
children under 2 years (up to 33do not use
lbs)

## Other information

- each caplet contains: calcium 165 mg, sodium 4 mg
- store between 20° to 25°C (68° to 77°F). Protect from light.

 do not use if carton is opened or if individual blister units are torn or opened

#### Inactive ingredients

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate anhydrous, flavor, microcrystalline cellulose, stearic acid.

#### **Questions or comments?**

call 1-888-287-1915

(Monday - Friday 8:30 AM to 5:00 PM EST)

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

Made in India

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg/125mg (24 Caplets) Blister Carton Label

NDC 79903-223-24

Compare to Imodium<sup>®</sup> Multi-Sympton Relief active ingridients<sup>\*\*</sup>

equate<sup>™</sup>

Loperamide Hydrochloride and Simethicone Tablets 2 mg/125 mg

Anti-Diarrheal/ Anti-Gas

Multi-Sympton Relief Caplet

Relieves symptoms of diarrhea *plus* 

- Cramps & Pressure
- Bloating
- Gas

#### Actual Size

#### 24 CAPLETS\* \*capsule-Shaped Tablets



LOPERAMIDE HYDRO		D SIMETH	ICONE		
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:79903-223		)3-223	
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name			Basis of St	rength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)			LOPERAMIDE HYDROCHLORIDE		2 mg
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10) DIMETHICONE				125 mg	

Inactive Ingredients				
	Ingredient Name			
ACESULFAME POTAS	<b>5SIUM</b> (UNII: 230V73Q5G9)			
CROSCARMELLOSE	SODIUM (UNII: M28OL1HH48	)		
ANHYDROUS DIBASI	C CALCIUM PHOSPHATE (L	INII: L11K75P92J)		
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)				
MICROCRYSTALLINE	CELLULOSE 102 (UNII: PNF	R0YF693Y)		
STEARIC ACID (UNII:	4ELV7Z65AP)			
<b>Product Charac</b>	teristics			
Color	WHITE (off-white)	Score	2 pieces	
		C!	1 7	

Color	WHITE (off-white)	Score	2 pieces
Shape	CAPSULE	Size	17mm
Flavor	VANILLA	Imprint Code	T;79
Contains			

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-223- 12	2 in 1 CARTON	02/17/2024	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:79903-223- 24	4 in 1 CARTON	02/17/2024	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211059	02/17/2024	

Labeler - WALMART INC. (051957769)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(79903-223), MANUFACTURE(79903-223)

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