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

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[®] Multi-Sympton Relief active ingridients^{**}

equate[™]

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	5SIUM (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)			
Product Charac	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)

-