LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet
FSA store INC

Loperamide Hydrochloride and Simethicone Tablets, 2 mg/125 mg (OTC)

ACTIVE INGREDIENT(S)

(in each tablet)
Loperamide Hydrochloride USP 2 mg
Simethicone USP 125 mg

PURPOSES

Anti-diarrheal
Anti-gas

USE(S)

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 hydrochloride
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 aretaking 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 tablet

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 over	2 tablets after the first loose stool; 1 tablet after each subsequent loose stool; but no more than 4 tablets in 24 hours
children 9-11 years (60-95 lbs)	1 tablet after the first loose stool; 1/2 tablet after each subsequent loose stool; but no more than 3 tablets in 24 hours
children 6-8 years (48-59 lbs)	1 tablet after the first loose stool; 1/2 tablet after each subsequent loose stool; but no more than 2 tablets 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

- each tablet contains: **calcium 640 mg, very low sodium and potassium 5.838 mg**
- store between 20 to 25°C (68 to 77°F). Protect from light.

- **do not use if carton is open or if blister unit is open or torn**

INACTIVE INGREDIENTS

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, microcrystalline cellulose, stearic acid and vanilla flavor

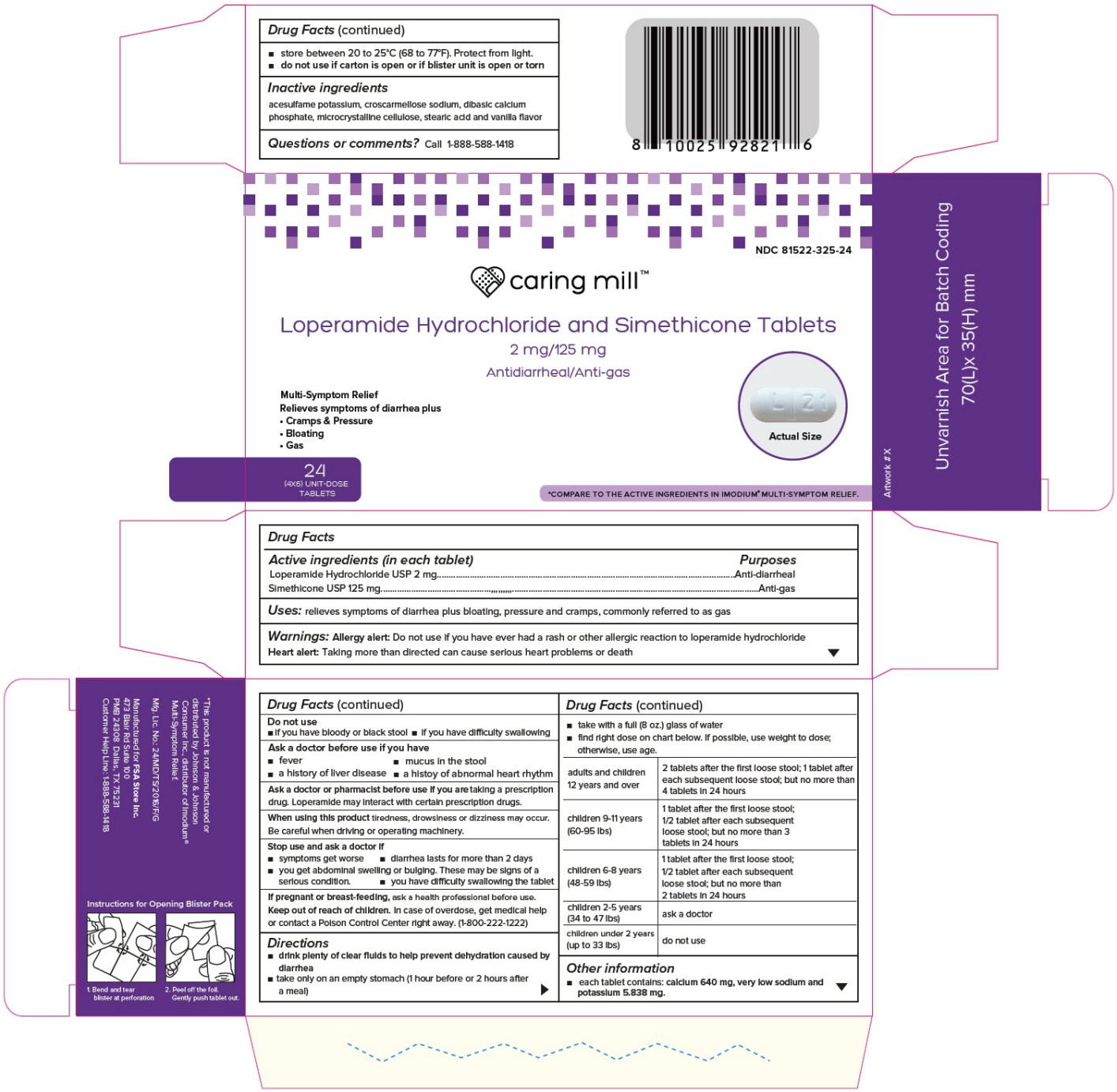
QUESTIONS OR COMMENTS

call **1-888-588-1418**

Manufactured for **FSA Store Inc.**
473 Blair Rd Suite 100
PMB 24308 Dallas, TX 75231
Customer Help Line: 1-888-588-1418

PRINCIPAL DISPLAY PANEL

Loperamide Hydrochloride and Simethicone Tablets 2 mg/125 mg-1x6's carton



Loperamide Hydrochloride and Simethicone Tablets 2 mg/125 mg-6's foil

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81522-325
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

DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	CAPSULE	**Size**	17mm
Flavor	VANILLA	**Imprint Code**	H;L21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81522-325-24	4 in 1 CARTON	06/30/2024	
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	ANDA211438	06/30/2024	

Labeler - FSA store INC (049283340)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(81522-325)

Revised: 4/2025 FSA store INC