LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE - loperamide hydrochloride and simethicone tablet
Camber Consumer Care 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 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 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**

Distributed by:

Camber Consumer Care, Inc.

Piscataway, NJ 08854, USA.

PRINCIPAL DISPLAY PANEL

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

LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE

loperamide hydrochloride and simethicone tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69230-325
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)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (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:69230-325-04	1 in 1 CARTON	06/17/2021	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69230-325-08	2 in 1 CARTON	06/17/2021	
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69230-325-06	1 in 1 CARTON	06/17/2021	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:69230-325-12	2 in 1 CARTON	06/17/2021	
4		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:69230-325-18	3 in 1 CARTON	06/17/2021	
5		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:69230-325-24	4 in 1 CARTON	06/17/2021	
6		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	06/17/2021	

Labeler - Camber Consumer Care Inc (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(69230-325)

Revised: 9/2022 Camber Consumer Care Inc