

INNOBLE ONECHEWTOOTHPASTE- sodium fluoride tablet livmate

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENT

Silicon Dioxide, Tetrasodium Pyrophosphate, Pyridoxine Hydrochloride, Sodium Fluoride

INACTIVE INGREDIENT

D-Sorbitol, Sodium Cocoyl Glutamate, Sodium Cocoyl Isethionate, Microcrystalline Cellulose, Xylitol, Magnesium Stearate, Sodium Bicarbonate, Xanthan Gum, Hydroxypropylcellulose, Enzymatically Modified Stevia, L-Menthol, Bamboo Salt, Sodium Chloride, DL-Malic Acid, Combined Flavor(Coolmint Flavor Powder), Combined Flavor(Lemon Flavor Powder), Coconut Oil, Aloe Vera Gel, Carrot Extract, Calendula Extract

PURPOSE

Anti plaque

Tartar Control

Anti Cavity

Against gum disease

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

WARNING

Do not use for children under 6 years of age.

Directions

Adults and children 6 years of age and older; Gently chew 1 tablet until it crushed. Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

INDICATION & USAGE SECTION

Prevention of cavities, plaque, gum disease, gingivitis and periodontal disease.



INNOBLE ONECHEWTOOTHPASTE

sodium fluoride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82709-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.22 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	5 g in 100 g
SODIUM PYROPHOSPHATE (UNII: O352864B8Z) (PYROPHOSPHORIC ACID - UNII:4E862E7GRQ)	SODIUM PYROPHOSPHATE	1 g in 100 g
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	0.05 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
XYLITOL (UNII: VCQ006KQ1E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MALIC ACID (UNII: 817L1N4CKP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARROT (UNII: L56Z1JK48B)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82709-001-01	84 g in 1 POUCH; Type 0: Not a Combination Product	05/03/2022	
2	NDC:82709-001-03	1 in 1 CARTON	05/03/2022	
2	NDC:82709-001-02	42 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/03/2022	

Labeler - livmate (987587873)

Registrant - livmate (987587873)

Establishment

Name	Address	ID/FEI	Business Operations
SUNGWON PHARMACEUTICAL CO., LTD.		689787898	manufacture(82709-001)

Revised: 5/2022

livmate