

MASTIKIS MASTIC GUMCARE- silicon dioxide, aminocaproic acid paste, dentifrice
Mastic Korea.Co.Ltd

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.

79814-009_Mastikis Mastic GumCare Toothpaste

Silicon Dioxide 16%

Aminocaproic Acid 0.1%

D-Sorbitol Solution, Glycerin, Carboxymethylcellulose Sodium, Corn Starch, Xylitol, Steviol Glycoside, Sodium Ascorbate, Hydroxyapatite, Sodium Bicarbonate, L-Menthol, Mastic Oil, Mentha Oil, Olive Oil, Eucalyptus Oil, Grapefruit Seed Extract, Glycyrrhiza Extract, Sodium Cocoyl Glutamate, Sodium Lauroyl Sarcosinate, Deionized Water

Keep out of Reach of Children.

Anti-cavity

Anti-gingivitis

Ask a dentist before use if you have

- bleeding or redness lasting more than 2 weeks pain, swelling, pus, loose teeth, or more spacing between teeth
- These may be signs of periodontitis, a serious form of gum disease
- Healthier teeth and gums, and better oral hygiene.
- Anti-caries, anti-plaque, anti-gingivitis
- Prevents periodontal and gum disease

Brush teeth with a pea-sized amount



MASTIKIS MASTIC GUMCARE

silicon dioxide, aminocaproic acid paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79814-009
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XB4) (SILICON DIOXIDE - UNII:ETJ7Z6XB4)	SILICON DIOXIDE	16 g in 100 g
AMINOCAPROIC ACID (UNII: U6F3787206) (AMINOCAPROIC ACID - UNII:U6F3787206)	AMINOCAPROIC ACID	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
STARCH, CORN (UNII: O8232NY3SJ)	
XYLITOL (UNII: VCQ006KQ1E)	
STEVIOSIDE (UNII: 0YON5MXJ9P)	
SODIUM ASCORBATE (UNII: S033EH8359)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
LICORICE (UNII: 61ZBX54883)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79814-009-02	1 in 1 CARTON	08/10/2021	
1	NDC:79814-009-01	120 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/10/2021	

Labeler - Mastic Korea.Co.Ltd (687791189)

Registrant - Mastic Korea.Co.Ltd (687791189)

Establishment

Name	Address	ID/FEI	Business Operations
Sungwon Pharmaceutical Co., Ltd.		689787898	manufacture(79814-009)

Revised: 8/2021

Mastic Korea.Co.Ltd