

MASTIKIS GOLD- 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.

79814-001_mastikis gold toothpaste

Aminocaproic Acid 0.1%
Silica 16%

D-Sorbitol Solution, Deionized Water, Glycerin, Mastic oil, Sodium Lauryl Sulfate, Polyethylene Glycol1500, Carboxymethylcellulose Sodium, Grapefruit Seed Extract, Xylitol, Steviol Glycoside, Hydroxyapatite, L-Menthol, Ascorbic Acid, Tocopherol Acetate

Keep out of Reach of Children.

Anti-cavity

Anti-plaque

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Aids in the cleanness of teeth and protection of gum health

Supervise children as necessary until capable of using without supervision.



MASTIKIS GOLD
silicon dioxide, aminocaproic acid paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79814-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	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)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
XYLITOL (UNII: VCQ006KQ1E)	
STEVIO SIDE (UNII: 0YON5MXJ9P)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79814-001-02	1 in 1 CARTON	07/31/2020	
1	NDC:79814-001-01	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		07/31/2020	

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(79814-001)

