

**MASTIKIS GOLD II- silicon dioxide, tetrasodium pyrophosphate 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](#).*

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**79814-002\_Mastikis Gold II toothpaste**

Silicon Dioxide 14.0%

Tetrasodium Pyrophosphate 0.5%

Tocopherol Acetate, D-Sorbitol Solution, Glycerin, Polyethylene Glycol1500,  
Carboxymethylcellulose Sodium, Trisodium Citrate, Xylitol, Steviol Glycoside, Bioactive Herb  
Complex-C(BHC-C), Hydroxyapatite, L-Menthol, Mastic oil, Grapefruit Seed Extract, Sodium Lauroyl  
Sarcosinate, Sodium Cocoyl Glutamate, Deionized Water

Keep out of Reach of Children.

Anti-plaque

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

Brighter and healthier teeth and better oral hygiene

Anti-caries, anti-plaque, anti-gingivitis

Prevents periodontal and gum disease

Brush teeth with a pea-sized amount



## MASTIKIS GOLD II

silicon dioxide, tetrasodium pyrophosphate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79814-002
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	14 g in 100 g
SODIUM PYROPHOSPHATE (UNII: O352864B8Z) (PYROPHOSPHORIC ACID - UNII:4E862E7GRQ)	SODIUM PYROPHOSPHATE	0.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
XYLITOL (UNII: VCQ006KQ1E)	

<b>STEVIO SIDE</b> (UNII: 0YON5MXJ9P)	
<b>LEVOMENTHOL</b> (UNII: BZ1R15MTK7)	
<b>CITRUS PARADISI SEED</b> (UNII: 12F08874Y7)	
<b>SODIUM LAUROYL SARCO SINATE</b> (UNII: 632GS99618)	
<b>SODIUM CO COYL GLUTAMATE</b> (UNII: BMT4RCZ3HG)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79814-002-02	1 in 1 CARTON	08/13/2020	
1	NDC:79814-002-01	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		08/13/2020	

**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(79814-002)

Revised: 8/2020

Mastic Korea.Co.Ltd