

**MASTIKIS MASTIC 24K WHITENING- hydrogen peroxide solution, tocopherol acetate, colloidal silicon dioxide 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.

79814-008_Mastikis Mastic 24K Whitening Toothpaste

Colloidal Silicon Dioxide 7%

Hydrogen Peroxide Solution 2.14%

Tocopherol Acetate 0.2%

D-Sorbitol Solution, Water, Glycerin, Mastic Oil, PCarboxymethylcellulose Sodium, Xantahan Gum, Polysorbate 60, Titanium Oxide, Citric Acid, Zylitol, Steviol Glycoside, Grapefruit Seed Extract, Sodium Lauroyl Sarcosinate, Sodium Cocoyl Glutamate, Mentha Oil, Spearmint oil, Tocopherol Acetate, Hydroxyapatite, L-Menthol, Eucalyptus Oil, Phytonside flavour, Glycyrrhiza Extract

Keep out of Reach of Children.

Anti-gingivitis

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

50X40X175



MASTIKIS MASTIC 24K WHITENING

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:798 14-008
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	2.14 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE	0.2 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
STEVIO SIDE (UNII: 0YON5MXJ9P)	
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
SPEARMINT OIL (UNII: C3M81465G5)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
LICORICE (UNII: 61ZBX54883)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79814-008-02	1 in 1 CARTON	01/28/2021	
1	NDC:79814-008-01	110 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		01/28/2021	

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(79814-008)

