

MASTIKIS FRESH GARGLE- cetylpyridinium chloride mouthwash
Mastic Korea.Co.Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

79814-007_Mastikis fresh gargle

Active ingredient

Cetylpyridinium chloride 0.05%

Purpose

Antigingivitis, Antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

Ask a dentist before use if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. These may be signs of symptoms of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. These may be signs of symptoms of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age

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

Directions

- adults and children 6 years & older: rinse for 30 seconds with 20 mL (4 teaspoonfuls) twice a day
- do not swallow
- children 6 years to under 12 years of age: supervise use
- when used after brushing, rinse mouth with water first
- children under 6 years of age: do not use consult a dentist or doctor

Other information

- this rinse is not intended to replace brushing or flossing

Inactive ingredients

Glycerin, Xylitol, Steviol Glycoside, Trisodium Citrate, Ascorbic Acid, L-Menthol, Green Tea

Extract, Mastic Oil, Lemon Mint Flavor, Sodium Benzoate, Hydrogenated Caster Oil, Deionized Water

principal display panel



MASTIKIS FRESH GARGLE			
cetylpyridinium chloride mouthwash			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79814-007
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII: CUB7J10JV3)		CETYL PYRIDINIUM CHLORIDE	0.5 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0K00R)			
GLYCERIN (UNII: PDC6A3C0OX)			
XYLITOL (UNII: VCQ006KQ1E)			
STEVIO SIDE (UNII: 0YON5MXJ9P)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
LEVOMENTHOL (UNII: BZ1R15MTK7)			
GREEN TEA LEAF (UNII: W2ZU1R8B0)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79814-007-02	20 in 1 PACKAGE	09/21/2020	
1	NDC:79814-007-01	10 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/21/2020	

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(79814-007)

Revised: 9/2020

Mastic Korea.Co.Ltd