

MASTIC DENT- sodium fluoride, eucalyptol, thymol and menthol mouthwash
Chia Gi 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.

Active Ingredients

Drug Facts:

Active Ingredients:

- Sodium Fluoride 0.025% - Anticavity
- Eucalyptol 0.092%, Menthol 0.042% - Antigingivitis , Antiplaque
- Thymol 0.064% - Antigingivitis, Antiplaque

Warnings

Warning:

- Do not use if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.
- Stop use and ask dentist if gingivitis, bleeding, or redness persists more than 2 weeks.

Keep out of reach.

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

Directions

Directions:

- Adults and children 12 of age and older - Vigorously swish 20mL (2.3 Fl. Oz or 4 tea-spoonfuls) between teeth for 30 seconds then spit out, do not swallow.
- Children under 12 years of age - Consult a dentist or doctor
- This rinse is not intended to replace brushing or flossing.

Other information

Other Information:

- Cold weather may cloud this product. Its anticeptic properties are not affected. Store at room temperature (25 C - 77 F).

Inactive Ingredients

Inactive Ingredients:

AQUA, Alcohol Denaturated, Sorbitol, Sodium Lauroyl Sarcosinate, Sodium Phosphate, Peg-40 Hydrogenated Castor Oil, Sodium Benzoate, Fragrance, Disodium EDTA, Sodium Saccharin, Pistacia

Lentiscus Mastic Gum, Pistacia Lentiscus Seed Oil, Acid Blue 9 CI 42090

Information of owner

Product Of Chios

CHIA GI LTD

144 AG. MINA, HIOS, 82100

GREECE

Tel.: 30-22710-33101, FAX: 30-22710-32229

www.masticspa.com

Made In Greece

PURPOSE SECTION

Reduces Gingivitis

Dosage

Dosage - Vigorously swish 20mL (2/3 Fl. OZ or 4 team - spoonfuls) between teeth for 30 seconds, then spit out do not swallow.

ImageofMouthwash.jpg

5.5x10.5 cm **C M Y K** PP λευκό ημιμάτ
CUT (overprint)

5.5x10.5 cm **C M Y K** PP λευκό ημιμάτ
CUT (overprint)

MASTIC DENT

sodium fluoride, eucalyptol, thymol and menthol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15304-4085
Route of Administration	ORAL, DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.25 mg in 1 mL
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
PISTACIA LENTISCUS SEED OIL (UNII: Z7D029774C)	
PISTACIA LENTISCUS RESIN (UNII: 7446H202QW)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALCOHOL (UNII: 3K9958V90M)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

Color	blue (Acid Blue 9 (CI 42090))	Score	
Shape		Size	
Flavor	MINT (Mint Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15304-4085-1	400 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/22/2005	

Labeler - Chia Gi LTD (363215270)

Registrant - Chia Gi LTD (363215270)