

**MASTIC DENT OULO ACTION- sodium fluoride paste, dentifrice
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 0.22% (0.12% w/v fluoride ion) - Anticavity

Warnings

Warnings:

- **When using this product**, if irritation occurs discontinue use.
- **Keep out of reach of children under 6 years of age.** If you accidentally swallow more than used for brushing, get medical help or contact a poison control Center right away.

Dosage

Use a pea-sized amount

Keep out of reach.

Keep out of reach of children under 6 years of age.

Directions

Directions:

- **Adults and children 2 years and older.**
- Brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician.
- Instruct in good brushing and rinsing habits (to minimize swallowing).
- **Children under 2 years** do not use unless directed by a dentist or a physician.

Inactive Ingredients

Inactive Ingredients:

Water, Sorbitol, Hydrated Silica, Glycerine, Peg-8, Fragrance, Sodium Lauryl Sarcosinate, Xanthan Gum, Titanium Dioxide, Chamomilla Recutita, Camelia Sinensis, Menthol Crystals, Sodium Saccharin, Allantoin, Pistacia Lentiscus (Mastic) Gum, Bisabolol, Glycyrrhetic Acid, Sodium Hydroxide

Information of owner

Product Of Chios

CHIA GI LTD

144 AG. MINA, HIOS, 82100

GREECE

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

PURPOSE SECTION

Aids in the prevention of dental cavities

Image of Label



26,95x14,55 cm

MASTIC DENT OULO ACTION

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15304-4681
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	2.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ENOXOLONE (UNII: P540XA09DR)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

ALLANTOIN (UNII: 344S277G0Z)
SORBITOL (UNII: 506T60A25R)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
XANTHAN GUM (UNII: TTV12P4NEE)
CAMELLIA SINENSIS SEED OIL (UNII: O5R6DK2M9K)
MENTHOL (UNII: L7T10EP3A)
PISTACIA LENTISCUS RESIN (UNII: 7446H202QW)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
.ALPHA.-BISABOLOL, ()- (UNII: 36HQN158VC)
CHAMOMILE (UNII: FGL3685T2X)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT (Mint Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15304-468 1-1	75 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/22/2005	

Labeler - Chia Gi LTD (363215270)

Registrant - Chia Gi LTD (363215270)

Establishment

Name	Address	ID/FEI	Business Operations
Chia Gi LTD		363215270	manufacture(15304-468 1) , label(15304-468 1) , pack(15304-468 1)