

**DENTI BUONGIORNO GUM CARE COOL MINT TOOTH- silica, sodium fluoride, tocopheryl acetate paste, dentifrice
ATOSAFE 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.

Active ingredient(s)

Silica 15.0%
Sodium Fluoride 0.22%
Tocopheryl Acetate 0.20%

Purpose

Antiplaque, Anticavity, Antigingivitis

Warnings

- Keep out of reach of children under 6 years of age.
- If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

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Use(s)

- Helps remove plaque and tartar buildup
- Helps prevent cavities
- Helps reduce gum inflammation and promote healthy teeth

Directions

- Adults and children 2 years of age and older : Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician
- Children 2 to 6 years : Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
- Children under 2 years : Ask a dentist or physician

Other Information

- Store at temperatures between 1°C and 30°C
- Use within 36 months from the date of manufacture
- Do not store in high/low temperatures or direct sunlight

Questions

+82-1588-9709

Inactive ingredients

D-Sorbitol Solution , Water(Aqua) , Silicon Dioxide, Concentrated Glycerin, Sodium Cocoyl Glutamate, Polyethylene Glycol 1500, Carboxymethylcellulose Sodium, Sodium Fluoride, Tocopherol Acetate, Sodium Bicarbonate, Hydrolyzed Collagen, Xylitol, Enzymatically Modified Stevia, Propolis Extract, Grapefruit Seed Extract, Aloe Extract,

Matricaria Extract, Eucalyptus Extract, Sage Extract, Green Tea Extract, Rosemary Extract, Calendula Extract, Leontopodium Alpinum Extract, Centella Extract, L-Menthol, Peppermint Oil, Cool-Mint Flavor, Aqua Mint Flavor, Sodium Lauroyl Sarcosinate



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85601-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ 1)	.ALPHA.-TOCOPHEROL ACETATE	0.2 g in 100 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.22 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C00X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85601-100-02	1 in 1 CARTON	01/02/2026	
1	NDC:85601-100-01	100 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		01/02/2026	

Labeler - ATOSAFE CO., Ltd (688995680)

Establishment

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO., LTD.		557810721	manufacture(85601-100)

Revised: 1/2026

ATOSAFE CO., Ltd