## DENTI BUONGIORNO GUM CARE 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.

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#### Active ingredient(s)

Silica 17.0%

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.

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

#### Use(s)

- Helps protect against cavities
- Helps reduce gum inflammation and maintain healthy gums
- Aids in the prevention of periodontal disease

#### **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 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

Sorbitol, Water, Glycerin, Sodium Cocoyl Glutamate, PEG-32, Cellulose Gum, Menthol, Mentha Piperita Oil, Sodium Lauroyl Sarcosinate, Stevioside, Sodium Bicarbonate, Cooling Flavor, Aqua Mint Flavor, Xylitol, Propolis Wax, Hydrolyzed Collagen, Chamomilla Recutita Flower Extract, Salvia Officinalis Leaf Extract, Camellia Sinensis Leaf Extract, Citrus

Paradisi Fruit Extract, Centella Asiatica Extract, Aloe Barbadensis Leaf Extract, Eucalyptus Globulus Leaf Extract, Calendula Officinalis Flower Extract, Rosmarinus Officinalis Leaf Extract



#### **DENTI BUONGIORNO GUM CARE TOOTH**

silica, sodium fluoride, tocopheryl acetate paste, dentifrice

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:85601-070 Route of Administration ORAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHATOCOPHEROL - UNII: H4N855PNZ 1)	.ALPHA TOCOPHEROL	0.2 g in 100 g
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15 g in 100 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.22 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)			
SORBITOL (UNII: 506T60A25R)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:85601-070- 02	1 in 1 CARTON	04/01/2025		
1	NDC:85601-070- 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		04/01/2025	

### Labeler - ATOSAFE CO., Ltd (688995680)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
DONG IL PHARMS CO., LTD.		557810721	manufacture(85601-070)	

Revised: 10/2025 ATOSAFE CO., Ltd