

**BEANGUARD SENSITIVE TOOTH PASTE- hydrated silica, potassium nitrate, sodium fluoride paste, dentifrice
BIO3S 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.

77935-401 BeanGuard Sensitive toothpaste

Active ingredients

Hydrated Silica 17.5%
Potassium Nitrate 5%
Sodium Fluoride 0.221%

Purposes

Hydrated Silica 17.5% Antiplaque
Potassium Nitrate 5% Antihypersensitivity
Sodium Fluoride 0.221% Anticavity

Uses

- builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact
- aids in the prevention of dental cavities
- helps interfere with harmful effects of plaque associated with gingivitis

Warnings

Do not use it for purposes other than intended.
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.
Stop use and ask a dentist if gingivitis, bleeding, or redness persists for more than 2 weeks.

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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 doctor.

Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).

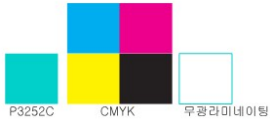
Supervise children as necessary until capable of using without supervision.

Children under 2 years of age: Consult a dentist or doctor.

Inactive ingredients

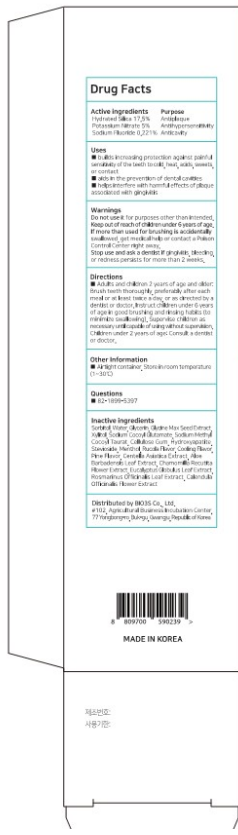
Sorbitol, Water; Glycerin, Glycine Max Seed Extract, Xylitol, Sodium Cocoyl Glutamate, Sodium Methyl Cocoyl Taurat, Cellulose Gum, Hydroxyapatite, Stevioside, Menthol, Rucola Flavor, Cooling Flavor, Pine Flavor, Centella Asiatics Extract, Aloe Barbadensis Leaf Extract, Chamomilla Recutita Flower Extract, Eucalyptus Globulus Leaf Extract, Rosmarinus Officinalis Leaf Extract, Calendula Officinalis Flower Extract

Display Panel



Case Info
48*37*180

Tube Info
미백치약 칼선
35파이 150mm



BEANGUARD SENSITIVE TOOTH PASTE

hydrated silica, potassium nitrate, sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77935-401
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 g in 100 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.221 g in 100 mL
HYDRATED SILICA (UNII: Y607T4G8P9) (HYDRATED SILICA - UNII:Y607T4G8P9)	HYDRATED SILICA	17.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3COOX)	

SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)
MARITIME PINE (UNII: 50JZ5Z98QY)
STEVIOSIDE (UNII: 0YON5MXJ9P)
MENTHOL (UNII: L7T10EIP3A)
SOYBEAN (UNII: L7HT8F1ZOD)
WATER (UNII: 059QF0KO0R)
XYLITOL (UNII: VCQ006KQ1E)
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)
SORBITOL (UNII: 506T60A25R)
EUCALYPTOL (UNII: RV6J6604TK)
CHAMOMILE (UNII: FGL3685T2X)
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)
ROSEMARY (UNII: IJ67X351P9)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
BRASSICA OLERACEA WHOLE (UNII: FQ4E5MHM9Q)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)
ALOE VERA LEAF (UNII: ZY81Z83H0X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77935-401-01	120 mL in 1 TUBE; Type 0: Not a Combination Product	12/27/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/27/2022	

Labeler - BIO3S Co.,Ltd. (694813103)

Registrant - BIO3S Co.,Ltd. (694813103)

Establishment

Name	Address	ID/FEI	Business Operations
BIO3S Co.,Ltd.		694813103	manufacture(77935-401)