

BEANGUARD GARGLE PLUS- sodium fluoride liquid
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.

77935-303 Beanguard Gargle Plus

Active Ingredient

Sodium Fluoride 0.05%

Purpose

Anticavity

Use

Aids in the prevention of dental cavities. Helps to refresh your breath.

Warnings

Do not use more or for longer than directed.

Warnings

This product contains fluorine, so if more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Warnings

Stop use and ask a dentist if oral irritation or tooth sensitivity occurs.

Warnings

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

Inactive Ingredients

Water, D-Sorbitol Solution, Concentrated Glycerin, Soybean Extract, Ethanol, Xylitol, Raspberry Extract, Sodium Alginate, Polyoxyethylene hydrogenated castor oil, Flavor, Sodium Benzoate, Menthol Pulegium Oil, L-Menthol, Sucralose, Sodium Fluoride, Citric acid, Sodium citrate, Green Tea Extract, Aloe Extract, Sage Extract

Other Information

Store in an airtight container at room temperature (1~30°C).

Directions

Vigorously swish 10 mL of gargle between your teeth for 1 minute and then spit it out.
Do not swallow.

Warnings

Do not swallow.

Label



BEANGUARD GARGLE PLUS

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77935-303
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.05 g in 100 mL
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Inactive Ingredients

Ingredient Name	Strength
SOYBEAN (UNII: L7HT8F1ZOD)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
PENNYROYAL OIL (UNII: AK85U7Y3MV)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ALOE (UNII: V5VD430YW9)	
CLARY SAGE (UNII: U3HSK5JC0Q)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
RASPBERRY (UNII: 4N14V5R27W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77935-303-01	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2022	
2	NDC:77935-303-02	10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/08/2022	

Labeler - BIO3S Co.,Ltd. (694813103)