

XEROSTOM- sodium fluoride mouthwash

Bio Cosmetics

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.

Xerostom Mouthwash

Active Ingredient

Sodium Fluoride 0.055%

Purpose

Anticavity Rinse

Keep out of reach of children.

Indications and Uses aids in the prevention of dental cavities

Warnings

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older: Use once a day after brushing your teeth with toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.

Inactive ingredients Water, Betaine, Glycerin, Peg-40 Hydrogenated Castor Oil, Propylene Glycol, Xylitol, Aroma, Potassium Phosphate, Diazolidinyl Urea, Allantoin, Olive oil, Sodium Methyl paraben, Sodium Propyl Paraben, Chlorophyll, D-Panthenol, Tocopheryl Acetate, Sucralose, Parsley Oil.

Other information store below 25°C (77°F)

Questions? info@biocosmetics.es

USA/Canada Toll Free: 1-855-688-5385 weekdays from 6.00 a.m. to 2.00 p.m.

Packaging

Drug Facts Active Ingredient Sodium Fluoride 0.055% Purpose Anticavity rinse Indications and Uses aids in the prevention of dental cavities Warnings Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away. Directions Adults and children 6 years of age and older: Use once a day after brushing your teeth with toothpaste. Vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.	Drug Facts (Continued) Other information store below 25°C (77°F) Inactive Ingredients Water, Betaine, Glycerin, Peg-40 Hydrogenated Castor Oil, Propylene Glycol, Xylitol, Aroma, Potassium Phosphate, Diazolidinyl Urea, Allantoin, Olive oil, Sodium Methyl paraben, Sodium Propyl Paraben, Chlorophyll, D-Panthenol, Tocopheryl Acetate, Sucralose, Parsley Oil. Questions? info@biocosmetics.es USA / Canada Toll Free: 1-855-688-5385 weekdays from 6:00 a.m. to 2:00 p.m. www.xerostom.com · info@biocosmetics.es XEROSTOM and Saliactive are trademarks of Bio Cosmetics, S.L. Made in Spain. Patented: US 6,350,435; US 8,540,970; US 6,432,388. Bio Cosmetics, S.L. C/Azaquil, 11, 28023 Madrid, Spain. AL21431000020/0
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XEROSTOM[®]

with *Saliactive*[®]

anticavity mouthwash
0.51 fl oz (15mL)

NATURE'S MOISTURIZER FOR DRY MOUTH & XEROSTOMIA

XEROSTOM

sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61041-211
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.559 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BETAINE (UNII: 3SCV180C9W)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
XYLITOL (UNII: VCQ006KQ1E)	
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALLANTOIN (UNII: 344S277G0Z)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
CHLOROPHYLL (UNII: 00WNZ48OR9)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PARSLEY OIL (UNII: IXK9N7RJ7J)	

Product Characteristics	
Color	Score

Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61041-211-31	15 mL in 1 PACKET; Type 0: Not a Combination Product	02/06/2015	10/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/06/2015	10/31/2024

Labeler - Bio Cosmetics (513423178)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS COSMODENT SL		513012153	manufacture(61041-211)

Revised: 8/2023

Bio Cosmetics