

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 Section

Anticavity Rinse

Keep out of reach of children

Keep out of reach of children 12yrs of age and under

Indications & Usage Section

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children 12 years of age and under.
For external use only. If you accidentally swallow more than used for rinsing, get medical help or contact a Poison Control Center immediately.
Do not use if you are allergic to any of the ingredients.

Dosage and administration

Adults and children over 12 years use at least twice a day after brushing.
Pour 10 milliliters; vigorously swish 10milliliters of rinse between teeth for 1 minute.
Then spit out.

Inactive Ingredient

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.

Principal Display panel



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
-----------------	----------	----------

Ingredient Name	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:61041-211-09	1 in 1 CARTON	11/15/2013	10/31/2024
1		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/15/2013	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