

**XEROSTOM- sodium fluoride paste**  
**Bio Cosmetics S L**

*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.*

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**Xerostom Toothpaste**

**Active Ingredient**

Sodium Fluoride 0.22%

**Purpose**

Anticavity

**Keep out of reach of children.**

**Indications & Uses** aids in the prevention of dental cavities

**Warnings**

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

**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 year of age: Consult a dentist or doctor.


**Inactive Ingredients** Glycerin, Water, Hydrated Silica, Xylitol, Betaine, Tetrapotassium Pyrophosphate, Olive Oil, Xanthan Gum, Titanium Dioxide, Potassium Phosphate, Flavor, Diazolidinyl Urea, Papain, Parsley Oil, D-Panthenol, Tocopheryl Acetate.

**Questions?** [info@biocosmetics.es](mailto:info@biocosmetics.es)

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

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

**Packaging**

<b>Drug Facts</b>	<b>Drug Facts (Continued)</b>
<b>Active Ingredient</b> Purpose Sodium Fluoride 0.22% Anticavity	<b>Other Information</b> store below 25°C (77°F)
<b>Indications and Uses</b> aids in the prevention of dental cavities	<b>Inactive Ingredients</b> Glycerin, Water, Hydrated Silica, Xylitol, Betaine, Tetrapotassium Pyrophosphate, Olive Oil, Xanthan Gum, Titanium Dioxide, Potassium Phosphate, Flavor, Diazolidinyl Urea, Papain, Parsley Oil, D-Panthenol, Tocopheryl Acetate.
<b>Warnings</b> 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.	<b>Questions?</b> info@biocosmetics.es USA / Canada Toll free: 1-855-688-5385 weekdays from 6:00 a.m. to 2:00 p.m.
<b>Directions</b> 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.	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/ Araquil, 11, 28023 Madrid, Spain.
<b>DETERGENT FREE = NO FOAM</b>	 AL21003000020/b



## XEROSTOM

sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61041-212
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	2.2 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POTASSIUM PHOSPHATE, UNSPECIFIED FORM</b> (UNII: B7862WZ632)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>PAPAIN</b> (UNII: A236A06Y32)	
<b>PARSLEY OIL</b> (UNII: IXK9N7RJ7J)	
<b>DEXPANTHENOL</b> (UNII: 1O6C93RI7Z)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	LEMON	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61041-212-03	6.5 g in 1 PACKET; Type 0: Not a Combination Product	02/06/2015	04/30/2025

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/06/2015	04/30/2025

**Labeler** - Bio Cosmetics S L (513423178)

## Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS COSMODENT SL		513012153	manufacture(61041-212)

Revised: 8/2023

Bio Cosmetics S L