

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.

Xerostom Toothpaste

Active Ingredient

Sodium Fluoride 0.22%

Purpose Section

Anticavity

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 brushing, 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 apply toothpaste onto a soft bristle toothbrush brush thoroughly after meals or at least twice a day or use as directed by a dentist or physician.
Children 12 years and under ask a dentist or physician. Once recommended, to minimize swallowing for children under 6, use a pea-sized amount and supervise brushing until good habits are established.

Inactive Ingredient

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.

Principal Display panel



Suitable for people suffering from mouth ulcers.

Suitable for vegetarians.

Detergent free.
No foam.

XEROSTOM[®]

with Saliactive[®]

anticavity
toothpaste



Drug Facts

Active ingredient Purpose
Sodium Fluoride 0.22%...Anticavity

Indications and Uses aids in the prevention of dental cavities

Warnings

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.

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.

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

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
USA / Canada Toll free:
1-855-688-5385
Weekdays from 6:00 am to 2:00 pm

XEROSTOM[®]

with Saliactive[®]

Hydrates, soothes and protects your mouth

The combined use of XEROSTOM products (toothpaste, mouthwash, gel and spray) for 1 week resulted in:

- A significantly increase in unstimulated whole salivary flow rates.
- Improvement of the overall dryness of the mouth, overall dryness of the tongue and level of thirst.
- Improvement of physical function, pain (related to dry mouth) and personal function¹.

Directions: Brush thoroughly with a soft toothbrush preferably for 3 minutes at least 3 times a day. When you are unable to brush, you can benefit from other XEROSTOM products: mouthwash, saliva substitute gel, saliva substitute spray, gum and tablets.

(1) J.A. Ship, et al. Journal of Oral Rehabilitation 2007 34:724-732. "Safety and effectiveness of topical dry mouth products containing olive oil, betaine, and xylitol in reducing xerostomia for polypharmacy-induced dry mouth".



XEROSTOM

sodium fluoride paste

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.2 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
XYLITOL (UNII: VCQ006KQ1E)	
BETAINE (UNII: 3SCV180C9W)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PAPAIN (UNII: A236A06Y32)	
PARSLEY OIL (UNII: IXK9N7RJ7J)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61041-212-01	1 in 1 CARTON	11/08/2013	04/30/2025
1		64 g in 1 TUBE; 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	11/08/2013	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