

ORAL7- sodium monofluorophosphate paste
JCEC Company, Inc.

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.

Oral7[®]

Drug Facts

Active Ingredient

Sodium Monofluorophosphate 0.76% w/w (1000ppmF)

Purpose

Anti-cavity

Use

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. If symptoms of dry mouth persist, consult a health care professional.

DO NOT use if you are allergic to any of the ingredients.

Directions

Adults and Children 2 years of age and older

- Use 2-3 times a day, 7 days a week.
- Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a doctor or dentist
- 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 77°F (25°C).

Ingredients

Sorbitol, Dicalcium Phosphate, Glycerin, Hydrated Silica, Dextrose Monohydrate, Silica, Isoceteth-20, Xylitol, Water, Cellulose Gum, Sodium Benzoate, Lactoperoxidase, Mentha Piperita (Peppermint Oil- includes limonene), Potassium Thiocyanate, Menthol, Lactoferrin, Lysozyme, Glucose Oxidase, Calcium Lactate

Questions or Comments?

Call Tel. : 908-420-3759 weekdays or, email us: info@fountainhealthcarellc.com

PRINCIPAL DISPLAY PANEL - 105 g Tube Carton

NDC 69297-000-19

Oral 7[®] Xylitol

balancing your mouth's natural flora

***Beneficial for the
whole family!***

- ☐ **No SLS (*harsh drying detergent*)**
- ☐ **With Fluoride & Calcium**
- ☐ **Extra Beneficial for Dry Mouth**

MOISTURIZING TOOTHPASTE

**With natural enzymes to
help reinforce your
mouth's own defense system**

75mL (105g) e

7 Reasons to use Oral7®

- ✓ For Dry Mouth sufferers – natural enzymes in Oral7® help reinforce the functions of healthy saliva
 - ✓ Up to 7 hours relief for mouth and throat dryness
 - ✓ Helps soothe and protect gums
 - ✓ Indication: Aids in the prevention of dental cavities.
- For maximum protection use in conjunction with alcohol-free Oral7® Moisturizing Mouthwash for longer lasting moisture use Oral7® Moisturizing Mouth Gel

Distributor:
 Fountain Health Care, LLC.
 Kendall Park, New Jersey 08824
www.fountainhealthcarellc.com
ALWAYS FOLLOW THE LABEL
 Questions or Comments?
 Tel.: 908-420-3759
info@fountainhealthcarellc.com
www.oral7.com

MADE IN UK



MOISTURIZING TOOTHPASTE

With natural enzymes to help reinforce your mouth's own defense system

NDC 69297-000-19



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MOISTURIZING TOOTHPASTE



With natural enzymes to help reinforce your mouth's own defense system

75mL (105g) e

Clears away the bacteria associated with Bad Breath, Sore Gums, Cavities and Plaque

Beneficial for the whole family



Made in UK

Drug Facts
Active Ingredient
 Sodium Monofluorophosphate
 0.296% w/w (1000ppm)
Purpose
 Anti-Cavity
Use
 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. If symptoms or signs persist, consult your healthcare professional. DO NOT use if you are allergic to any of the ingredients.
Directions
 Adults & children 2 years of age and older
 - Brush teeth thoroughly and evenly after each meal or at least twice a day, or as directed by a doctor or dentist.

Drug Facts (continued)
 - Instruct children under 6 years of age in good brushing and flossing habits to minimize swallowing. Supervise children as necessary until capable of doing without supervision.
Children under 2 years of age: Consult a dentist or doctor.
Other Information Store below 77°F (25°C).
Ingredients
 Sorbitol, Dicalcium Phosphate, Glycerin, Hydrated Silica, Dextrine Monohydrate, Silica, Boreboric Oxide, Mineral Water, Cellulose Gum, Sodium Benzoate, Lactoperoxidase, Mentha Piperita, Propylene Glycol, Sodium Fluoride, Potassium Thiocyanate, Menthol, Lactrimin, Xylitol, Xanthan Gum, Calcium Lactate.
Questions or Comments?
 Tel.: 908-420-3759 website: info.fountainhealthcarellc.com
 Always follow the label

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ORAL7
 balancing your mouth's natural flora

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MOISTURIZING TOOTHPASTE

With natural enzymes to help reinforce your mouth's own defense system

75mL (105g) e



077P75UCTN1

ORAL7

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69297-000
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.4 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOCETETH-20 (UNII: O020065R7Z)	
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MYELOPEROXIDASE (UNII: JQZ6YM58U5)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
POTASSIUM THIOCYANATE (UNII: TM7213864A)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
LACTOFERRIN, BOVINE (UNII: KG21X1090A)	
LYSOZYME (UNII: 968JKA7T33)	
GLUCOSE OXIDASE (UNII: 0T8392U5N1)	
CALCIUM LACTATE (UNII: 2URQ2N32W3)	

Product Characteristics

Color	WHITE (TO OFF WHITE)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69297-000-19	1 in 1 CARTON		

1	105 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	02/01/2015	

Labeler - JCEC Company, Inc. (961973299)

Revised: 1/2015

JCEC Company, Inc.