KIDS PRIME PEDIATRIC DENTAL GROUP ANTICAVITY FOR KIDS- sodium fluoride ointment Prime Tooth Care LLC

Kids Prime Pediatric Dental Group Anticavity Toothpaste for Kids

Drug Facts

Active Ingredient

Sodium fluoride 0.25%

Purpose

Anticavity

Use

helps protect against 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	Brush teeth thoroughly, preferably after each meal or at least
years of age and older	twice a day, or as directed by a dentist or doctor.
Children 2 to 6 years	Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
Children under 2 years	Ask a dentist or physician

Inactive ingredients

Sorbitol, Aqua, Hydrated Silica, PEG-300, Glycerin, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Sodium Benzoate, Carrageenan, Saccharin Sodium, Sodium Pyrophosphate, FD&C Blue No.1.

Other information

Store in a cool place, below 86°F, away from heat

Do not use if quality seal is broken or missing Do not use after the expiration date

Package Labeling: 25g



Drug Facts

Active Ingredient

Purpose

Sodium fluoride 0.25% Anticavity

Use helps protect against 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 physician

Children 2 to 6 years

Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years Ask a dentist or physician

Inactive ingredients Sorbitol, Aqua, Hydrated Silica, PEG-300, Glycerin, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Sodium Benzoate, Carrageenan, Saccharin Sodium, Sodium Pyrophosphate, FD&C Blue No.1.

Other information

Store in a cool place, below 86° F, away from heat Do not use if quality seal is broken or missing Do not use after the expiration date

Dist. by:

Prime Pediatric Dental Group

4410 W 16 th Ave Suite 47

Hialeah FL 33012 Made in PRC



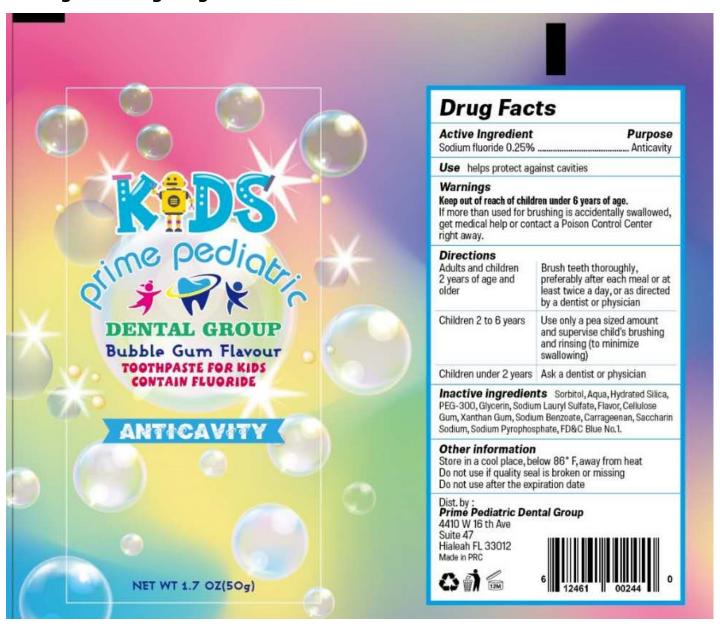






NET WT 0.88 OZ(25g)

Package Labeling: 50g



KIDS PRIME PEDIATRIC DENTAL GROUP ANTICAVITY FOR KIDS

sodium fluoride ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87053-008
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 14000 (UNII: 77HY82S0LG)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:87053-008- 00	1 in 1 BOX	08/31/2025		
1		25 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:87053-008- 01	1 in 1 BOX	08/31/2025		
2		50 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 Drug	M021	08/31/2025	

Labeler - Prime Tooth Care LLC (119575114)

Registrant - Prime Tooth Care LLC (119575114)

Revised: 8/2025 Prime Tooth Care LLC