

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 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.
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

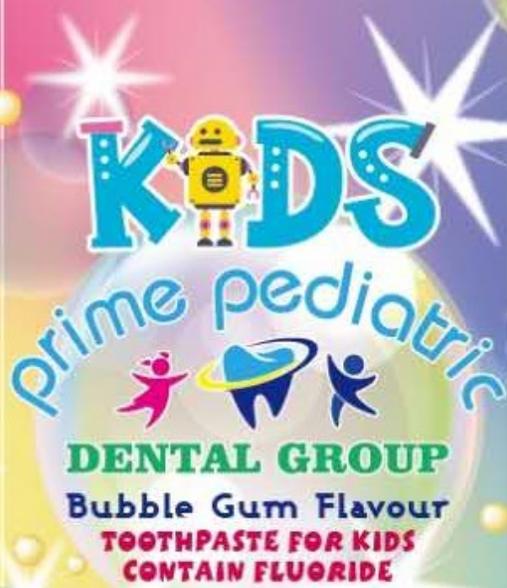
Sorbitol, Aqua, Hydrated Silica, PEG-300, Glycerin, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Sodium Benzoate, Carrageenan, Saccharin Sodium, Sodium Pyrophosphate, FD&C Blue No.1.

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



ANTICAVITY

NET WT 0.88 OZ(25g)

Drug Facts

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Sodium fluoride 0.25%	Anticavity

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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



Package Labeling: 50g

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	
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Dist. by : Prime Pediatric Dental Group 4410 W 16 th Ave Suite 47 Hialeah FL 33012 Made in PRC	

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:Q80VPU4080)	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: K679OBS311)	
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)	

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)