

**BUBBLE GUM FLAVOR FOR KIDS 25G 50G- bubble gum flavor toothpaste for kids 25g 50g ointment**  
**WORLD DENTISTS ASSOCIATION AMERICA LIMITED**

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**85215-001**

**Bubble Gum Flavor Toothpaste For Kids 25g&50g**

**Active Ingredient(s)**

Sodium Fluoride 0.25%

**Purpose**

Anticavity

**Use**

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.

**Do not use**

Do not apply on open skin wounds  
In case of contact with eyes, rinse eyes thoroughly with water.  
Minimize swallowing  
Keep out of reach of children under 6 years of age.

**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

**Other information**

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

Do not use if quality seal is broken or missing

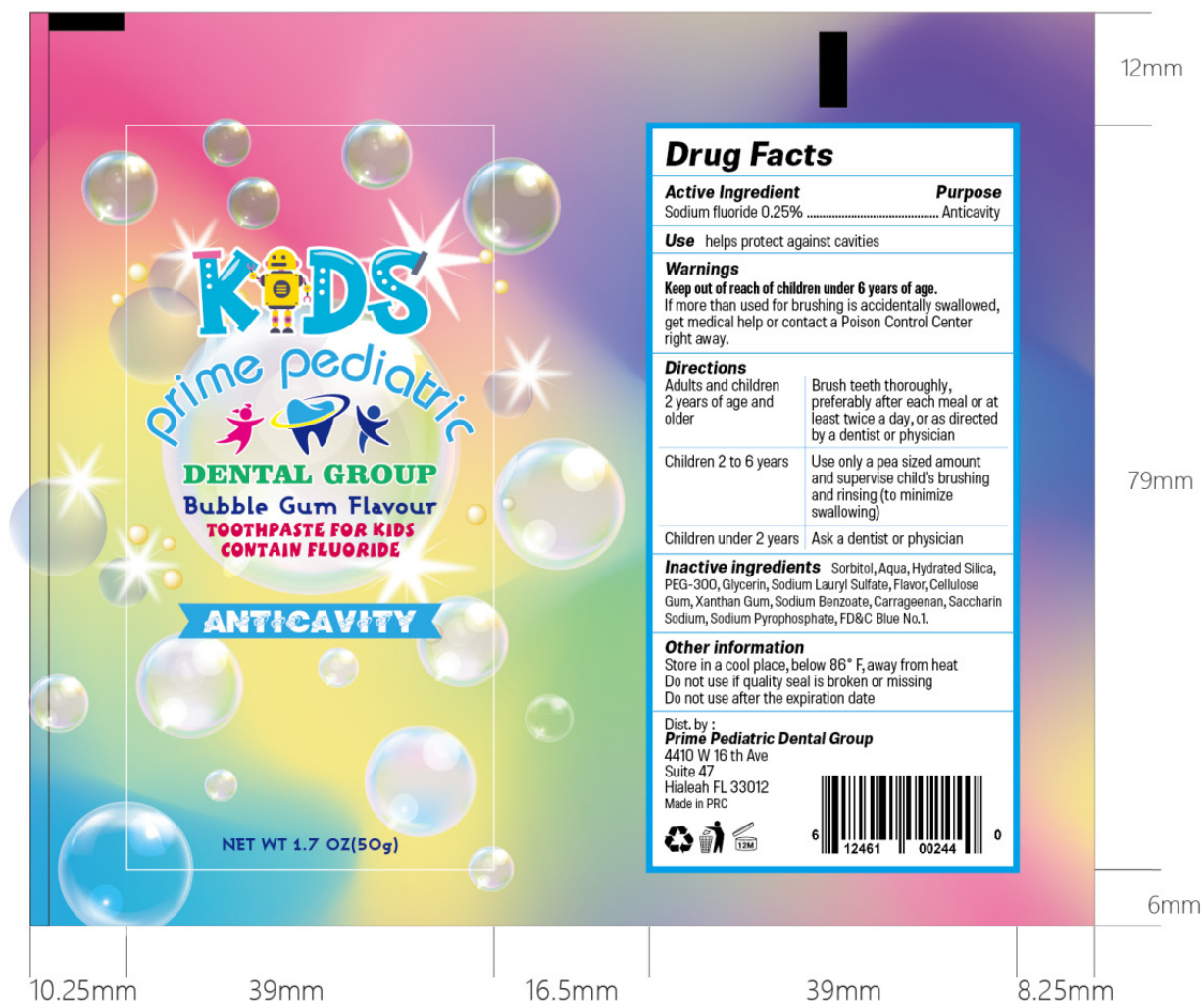
Do not use after the expiration date

**Inactive ingredients**

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.

**Package Label - Principal Display Panel**





## BUBBLE GUM FLAVOR FOR KIDS 25G 50G

bubble gum flavor toothpaste for kids 25g 50g ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85215-001
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.25 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM SACCHARIN</b> (UNII: SB8ZUX40TY)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>AQUA</b> (UNII: 059QF0KOOR)	

<b>SILICA</b> (UNII: ETJ7Z6XBU4)	
<b>POLYETHYLENE GLYCOL 14000</b> (UNII: 77HY82S0LG)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SCHISANDRA CHINENSIS FRUIT</b> (UNII: ABS794681C)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>CARRAGEENAN</b> (UNII: 5C69YCD2YJ)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85215-001-01	25 g in 1 TUBE; Type 0: Not a Combination Product	05/17/2025	
2	NDC:85215-001-02	50 g in 1 TUBE; Type 0: Not a Combination Product	05/17/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	05/17/2025	

**Labeler** - WORLD DENTISTS ASSOCIATION AMERICA LIMITED (663274349)

### Establishment

Name	Address	ID/FEI	Business Operations
WORLD DENTISTS ASSOCIATION AMERICA LIMITED		663274349	manufacture(85215-001)

Revised: 5/2025

WORLD DENTISTS ASSOCIATION AMERICA LIMITED