

PRIME TOOTH CARE SUMMER WATERMELON- sodium fluoride ointment
Prime Tooth Care LLC

Prime Tooth Care Toothpaste, Summer Watermelon

Drug Facts

Active Ingredient

Sodium fluoride 0.25% (1100PPM)

Purpose

Anticavity

Use

helps protect against cavities

Warnings

When using this product

- Do not swallow
- Do not use in eye area

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 use 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.

Inactive Ingredients

Sorbitol, Aqua, Hydrated Silica, Glycerin, Sodium Lauroyl Sarcosinate, Fragrance/ Flavor, Nano-Hydroxyapatite, Xanthan Gum, Menthol, Sodium Benzoate, Carboxymethyl Cellulose, Sodium Saccharin, Xylitol, Sodium Pyrophosphate, Red Dates Extract, Ginseng Extract, Hydrogen Peroxide (PVP - H2O2).

Package Labeling:

Nano-Hydroxyapatite
Fluoride Anti-Caries
Toothpaste

SUMMER WATERMELON

with natural ingredients

TOOTH
CARE

prime

Net wt. 2.3 oz (65 g)

Dist. by :
Prime Tooth Care
4410 W 16 th Ave
Suite 47
Hialeah FL 33012
Made in PRC

EXP: 06/2028





6 12461 13610 7

Drug Facts

Active Ingredient	Purpose
Sodium fluoride 0.25% (1100PPM)	Anticavity

Use helps protect against cavities

Warnings
When using this product ■ Do not swallow ■ Do not use in eye area

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 use 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.

Inactive Ingredients Sorbitol, Aqua, Hydrated Silica, Glycerin, Sodium Lauroyl Sarcosinate, Fragrance/ Flavor, Nano-Hydroxyapatite, Xanthan Gum, Menthol, Sodium Benzoate, Carboxymethyl Cellulose, Sodium Saccharin, Xylitol, Sodium Pyrophosphate, Red Dates Extract, Ginseng Extract, Hydrogen Peroxide (PVP-H2O2).



NON ANIMAL TEST ALCOHOL FREE PARABEN FREE SULFATE FREE

PRIME TOOTH CARE SUMMER WATERMELON			
sodium fluoride ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87053-007

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)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87053-007-00	1 in 1 BOX	08/31/2025	
1		65 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)