

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

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).



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: Y607T4G8P9) | |
| 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)