PRIME TOOTH CARE HAMI MELON- sodium fluoride ointment Prime Tooth Care LLC

Prime Tooth Care Toothpaste, Hami Melon

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 - H202).

Package Labeling:

Nano-Hydroxyapatite Fluoride Anti-Caries Toothpaste

O O O T A R E A

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



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NON ANIMAL T

PRIME TOOTH CARE HAMI MELON

sodium fluoride ointment

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:87053-003

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: 05JZ17B19X) | | | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | | | |
| XYLITOL (UNII: VCQ006KQ1E) | | | |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z) | | | |
| ASIAN GINSENG (UNII: CUQ3A77YXI) | | | |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | | | |

| F | Packaging | | | | | |
|---|----------------|---|-------------------------|-----------------------|--|--|
| # | tem Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:87053-003- | 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 | | |
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Labeler - Prime Tooth Care LLC (119575114)

Registrant - Prime Tooth Care LLC (119575114)

Revised: 8/2025 Prime Tooth Care LLC