

**SUPER VANILLA PRESCRIPTION- anticavity toothpaste paste, dentifrice
SuperMouth, LLC.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SuperMouth Super Vanilla Prescription Toothpaste

ACTIVE INGREDIENT

Sodium Fluoride 1.1% (5000 ppm)

PURPOSE

Sodium Fluoride Anticavity

USE: This medication is used as part of a professional program for the prevention and control of dental caries. Use as directed by your health professional.

WARNINGS: Do not swallow. Do not use in children under 6 years of age unless recommended by a dentist or physician. 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.

See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or physician.

DIRECTIONS: Use as directed by a dentist or physician.

INACTIVE INGREDIENTS

Glycerin, Water, Hydrated Silica, *Hydroxamin® (Nano-Hydroxyapatite, Menquinone-y (Vit K2), Cholecalciferol (Vit D3)), Xylitol, Inulin, Sodium Gluconate, Methylsulfonylmethane, Xanthan Gum, Quillaja Saponaria Extract, Natural Flavor, Natural Benzoic Acid, Sodium Ascorbate (Vit C), Stevia Leaf Extract, Cranberry Seed Oil.

*Patent-Pending Formulation

**PRINCIPAL DISPLAY PANEL - SuperMouth Super Vanilla Prescription
Toothpaste**

Supermouth Pro

1.1% sodium fluoride

5000 ppm

Anticavity Toothpaste

Rx Only

super vanilla

content: 1 tube 3.4oz (96g)

Dist by: SuperMouth®
9737 Aero Drive
San Diego, CA

844-MOUTHCARE
Made In The USA with
Domestic & global materials

Anticavity Toothpaste
super vanilla

Rx Only

SuperMouth

professional
SuperMouth

◆
prescription
strength cavity
protection
◆
for professional
use only



SuperMouth

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9737 Aero Drive
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844-MOUTHCARE
Made In The USA
with domestic &
global materials

1.1% sodium fluoride
5000 ppm

Anticavity Toothpaste



prescription fluoride+
hydroxamin*

Rx Only

super vanilla

content: 1 tube 3.4oz (96g)



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*patent-Pending Formulation



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*Patent-Pending Formulation

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domestic & global materials



8 10131 04087 1

0102802002-00

Supermouth

pro

1.1% sodium fluoride
5000 ppm

Anticavity Toothpaste



prescription fluoride+
hydroxamin*

Rx Only

super vanilla

content: 1 tube 3.4oz (96g)

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SUPER VANILLA PRESCRIPTION

anticavity toothpaste paste, dentifrice

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:83729-100

Route of Administration DENTAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION | 1.1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) | |
| MENAQUINONE 7 (UNII: 8427BML8NY) | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| INULIN (UNII: JOS53KRJ01) | |
| SODIUM GLUCONATE (UNII: R6Q3791S76) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| QUILLAJA SAPONARIA WHOLE (UNII: HIU9R169Y7) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| SODIUM ASCORBATE (UNII: S033EH8359) | |
| STEVIA LEAF (UNII: 6TC6NN0876) | |
| CRANBERRY SEED OIL (UNII: 73KDS3BW5E) | |

Product Characteristics

| | | | |
|----------|---------|--------------|--|
| Color | brown | Score | |
| Shape | | Size | |
| Flavor | VANILLA | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83729-100-10 | 1 in 1 CARTON | 10/13/2023 | |
| 1 | | 96 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 |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 10/13/2023 | |

Labeler - SuperMouth, LLC. (049384038)

Registrant - SuperMouth, LLC. (049384038)

Revised: 11/2024

SuperMouth, LLC.