## SUPER STRAWBERRY 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 Strawberry 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 Strawberry Prescription Toothpaste

Supermouth Pro

1.1% sodium fluoride

5000 ppm

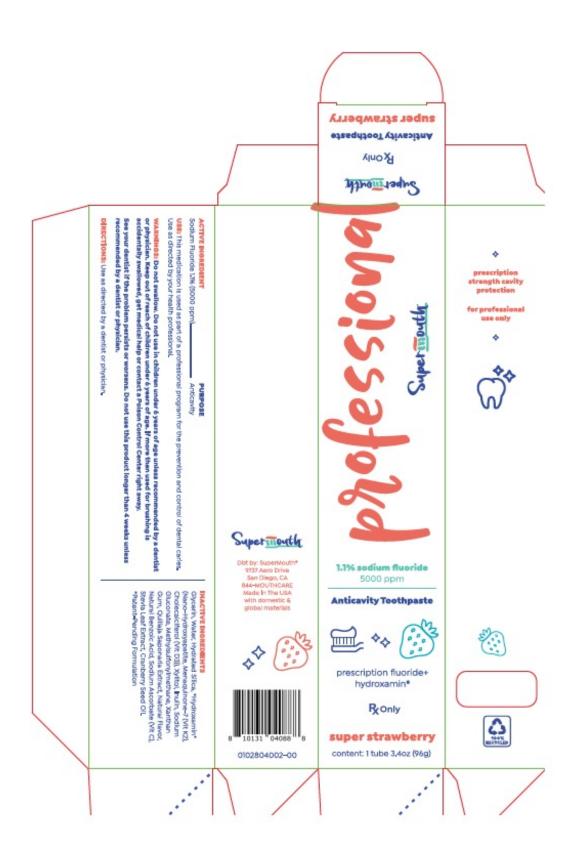
**Anticavity Toothpaste** 

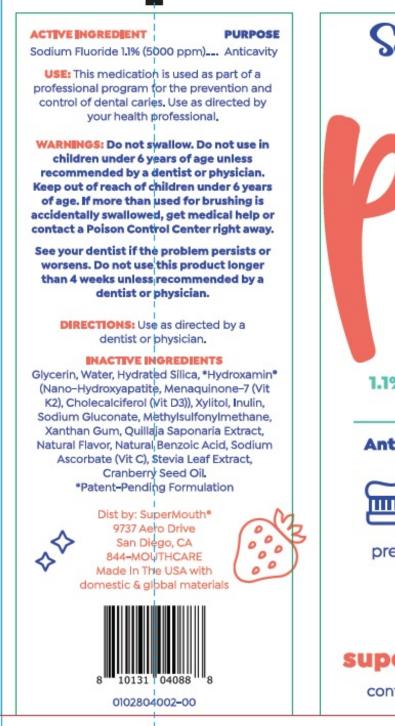
Rx Only

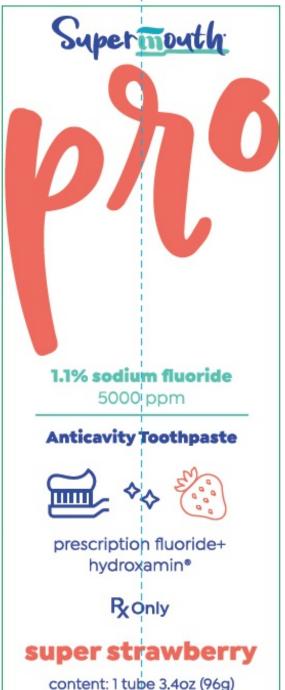
super strawberry

content: 1 tube 3.4oz (96g)

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







res

### SUPER STRAWBERRY PRESCRIPTION

anticavity toothpaste paste, dentifrice

**Product Information** 

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:83729-101
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: 85KN0B0MIM)			
SODIUM ASCORBATE (UNII: S033EH8359)			
STEVIA LEAF (UNII: 6TC6NN0876)			
CRANBERRY SEED OIL (UNII: 73KDS3BW5E)			

Product Characteristics			
Color	brown	Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83729-101- 10	1 in 1 CARTON	10/13/2023	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing In	Marketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug		10/12/2022	

other 10/13/2023

## Labeler - SuperMouth, LLC. (049384038)

### Registrant - SuperMouth, LLC. (049384038)

Revised: 10/2023 SuperMouth, LLC.