

**SUPER CHOCOLATE 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 Chocolate 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 Chocolate Prescription
Toothpaste**

Supermouth Pro

1.1% sodium fluoride

5000 ppm

Anticavity Toothpaste

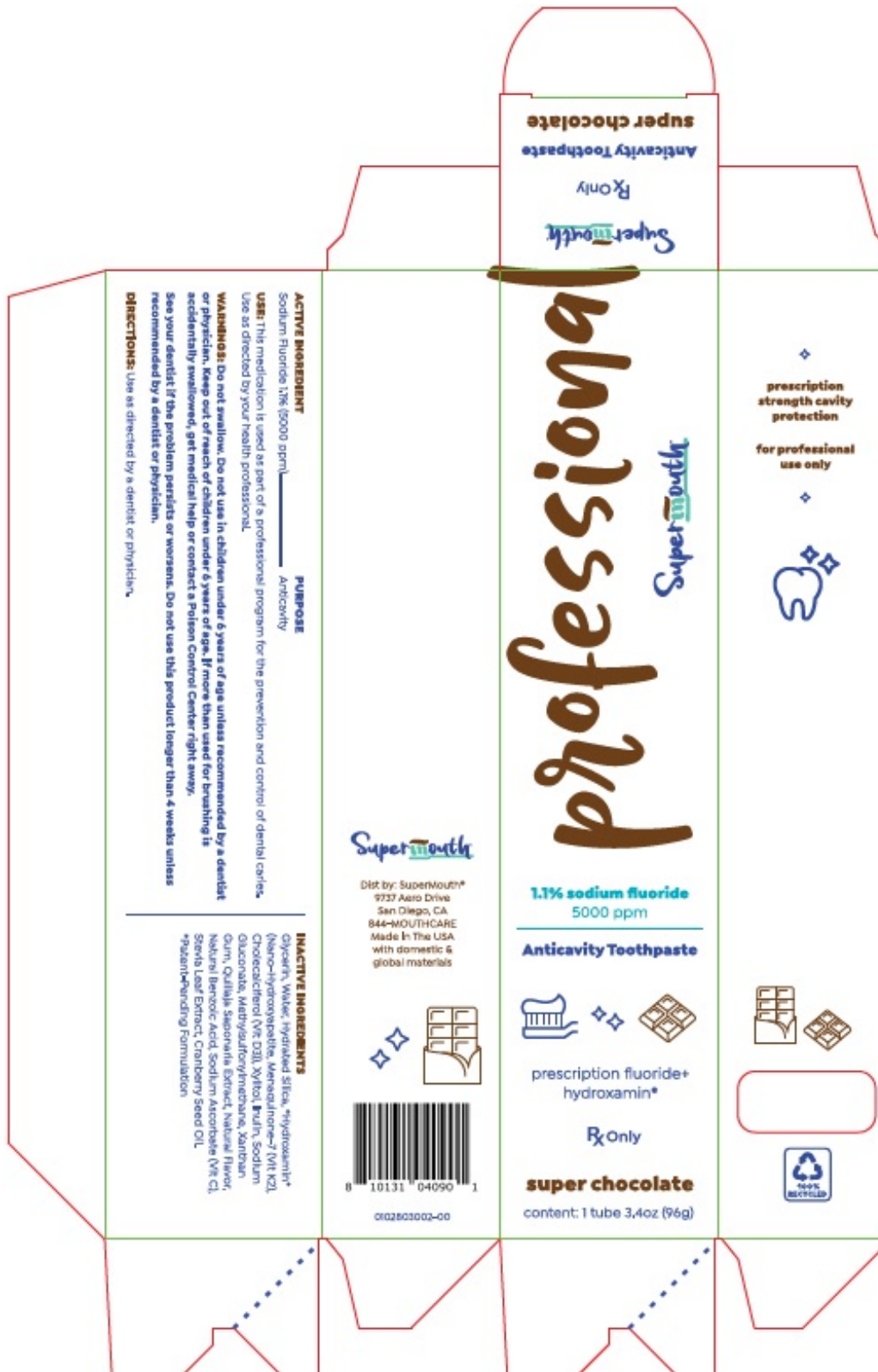
Rx Only

super chocolate

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 chocolate

Rx Only

SuperMouth

Professional

SuperMouth

prescription
strength cavity
protection

for professional
use only



SuperMouth

Dist by: SuperMouth®
9737 Aero Drive
San Diego, CA
844-MOUTHCARE
Made In The USA
with domestic &
global materials

1.1% sodium fluoride
5000 ppm

Anticavity Toothpaste



prescription fluoride+
hydroxamin*

Rx Only

super chocolate

content: 1 tube 3.4oz (96g)



ACTIVE INGREDIENT

Sodium Fluoride 1.1% (5000 ppm) _____ Anticavity

PURPOSE

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 it 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, *Hydroxylapatite, Nano-Hydroxyapatite, Menaquinone-7 (MK-7), Cholecalciferol (Vit D3), Xylitol, Sodium Gluconate, Methylsulfoniurethane, Xanthan Gum, Quilla Saponin Extract, Natural Flavor, Natural Peroxy Acid, Sodium Ascorbate (Vit C), Spearmint Extract, Cranberry Seed Oil, *Zincam®-Binding Formulation



0102503003-00

ACTIVE INGREDIENT

Sodium Fluoride 1.1% (5000 ppm)...

PURPOSE

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, Menaquinone-7 (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



Dist by: SuperMouth*
9737 Aero Drive
San Diego, CA
844-MOUTH-CARE
Made In The USA with
domestic & global materials



0102803002-00

Supermouth

pro

1.1% sodium fluoride
5000 ppm

Anticavity Toothpaste



prescription fluoride+
hydroxamin*

Rx Only

super chocolate

content: 1 tube 3.4oz (96g)

res

SUPER CHOCOLATE PRESCRIPTION

anticavity toothpaste paste, dentifrice

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:83729-103
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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	CHOCOLATE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83729-103-10	1 in 1 CARTON	10/13/2023	
1		96 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
------------------	--	------------------------	----------------------

Category	Citation	Date	Date
unapproved drug other		10/13/2023	

Labeler - SuperMouth, LLC. (049384038)

Registrant - SuperMouth, LLC. (049384038)

Revised: 11/2024

SuperMouth, LLC.