

ORAL PRO CARE- cavity protection gel gel

Den-Mat Holdings, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Stannous Flouride 0.4% (0.12% w/v flouride ion)

Purpose

Anticavity

Uses

Aids in the prevention of dental cavities

Warnings

This is an anticavity flouride prevent treatment gel, not a toothpaste. Read directions carefully before using.

Using this product may produce surface staining of the teeth. Adequate tooth brushing may prevent stains which are not harmful or permanent and may be removed by a dentist.

Keep out of reach of children section

Keep out of reach of children. 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 as directed by a dentist or doctor.
- Children under 2 years of age: Consult a dentist or doctor.
- Do not swallow.
- To minimize swallowing, use a pea-sized amount in children under 6.
- Instruct children under 6 years of age in good brushing and rinsing habits.
- Supervise children as necessary until

capable of using without supervision.

Other Information

For your protection, do not use if the tip under the cap is cut or tampered.

Inactive Ingredients

Ascorbic Acid, Carbomer, Citric Acid, Flavor, Glycerin, Triethanolamine

Questions or Comments?

800-433-6628

Principal Display Panel

OralProCare™

Clinical Strength

Cavity Protection Gel

Formulated with Stannous Flouride

Fresh Mint Flavor

Net Wt 4 oz.(113.4 g)

Labeling

OralProCare™

NDC 59883-600-04

Drug Facts

Active Ingredient	Purpose
Stannous Fluoride 0.4% (0.12% w/v fluoride ion)	Anticavity

Uses

Aids in the prevention of dental cavities.

Warnings

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Using this product may produce surface staining of the teeth. Adequate tooth brushing may prevent stains which are not harmful or permanent and may be removed by a dentist.

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Questions or comments?

800-433-6628

Manufactured for:
Den-Mat Holdings, LLC
1017 W. Central Avenue
Lompoc, CA 93436 USA 001399450 R:O 07/22SN
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CLINICAL STRENGTH
Formulated with
Stannous Fluoride

**FRESH MINT
FLAVOR**
Net Wt 4 oz. (113.4 g)

OralProCare™
cavity protection gel

No Copy - Overlap (color may bleed)

ORAL PRO CARE

cavity protection gel gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59883-600
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.969 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER 934 (UNII: Z135WF9208)	
GLYCERIN (UNII: PDC6A3C0OX)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59883-600-04	113.4 g in 1 TUBE; Type 0: Not a Combination Product	06/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/14/2023	

Labeler - Den-Mat Holdings, LLC (809857704)**Registrant** - Den-Mat Holdings, LLC (809857704)