DENTI-CARE DENTI-FOAM TOPICAL SODIUM FLUORIDE MINT- sodium fluoride aerosol, foam
AMD Medicom Inc.

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.

10037-M Mint Foam
DentiCare Pro-Foam 2.72 % Topical Sodium Fluoride

General Information

AMD Medicom Inc.

DentiCare Pro-Foam

2.72% Topical Sodium Fluoride Foam (1.23% Fluoride Ions)

Mint

4.4 oz / 125 g

NDC 64778-0376-1

NPN 80009738

Rx Only in US

Item code 10037-M

Indications and Directions

Indications: topical anti-caries preparation

Directions:

1. Following prophylaxis treatment, fill ¼ of tray with foam
2. To dispense, shake bottle vigorously then invert applicator 180° downward to the bottom of the tray
3. Insert tray, have patient bite down lightly for a minimum of 60 seconds, up to 4 minutes
4. Remove tray and have patient expectorate excess

Advise patient not to eat, drink or rinse for 30 minutes after the treatment

Medicinal ingredients: Fluoride ions 1.23% w/w (from 2.72% w/w sodium fluoride)

Non-Medicinal Ingredients

Water, sucralose, sodium phosphateic, xylitol, betaine, pluronic, mint peppermint oil, spearmint oil

Warnings

KEEP OUT OF REACH OF CHILDREN. For professional use only

Avoid spraying toward open flame. Store at room temperature. Do not expose to excessive heat over 40°C or 104°F

Contents under pressure. Do not puncture or incinerate

Do not use if seal is broken.

Contact Information

Made in USA for AMD Medicom Inc.
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Questions: 1-800-361-2862

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Principal Display Pannel

DENTI-CARE DENTI-FOAM TOPICAL SODIUM FLUORIDE MINT

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64778-0376
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0272 g in 1 g

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64778-0376-3	12 in 1 CASE	12/01/2017	05/31/2024
1	NDC:64778-0376-1	125 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2003	05/31/2024

Labeler - AMD Medicom Inc. (256880576)

Registrant - AMD Medicom Inc. (256880576)

Revised: 12/2023 AMD Medicom Inc.