

DENTI-CARE TOPICAL SODIUM FLUORIDE STRAWBERRY- sodium fluoride aerosol, foam

AR 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.

Denti-Care Denti-Foam 1.76 % Topical Sodium Fluoride Foam Strawberry

Denti-Care

Denti-Foam

1.76 % Topical Sodium Fluoride Foam

(1.23 % Fluoride Ions)

Strawberry

4.4 oz / 125 g

NDC 64778-1379-1

A topical anti-caries preparation

Directions (for professional use only):

1. Use after thorough prophylaxis
2. To dispense, shake bottle vigorously then invert applicator 180 degrees downward to the bottom of the tray(s)

Note: fill tray(s) at one quarter full to allow foam to expand

3. Insert tray(s) in mouth and have patient bite down lightly for 1 minute or up to 4 minutes
4. Remove tray(s) and have patient expectorate excess
5. Advise patient not to eat, drink or rinse for 30 minutes after the application

130 applications

Medicinal ingredients:

Fluoride ions 1.23 % w/w (from 1.76 % sodium fluoride and 1.04% hydrofluoric acid)

Non-Medicinal ingredients: sodium saccharin, sodium benzoate, plasdone C30, glycerin USP, propylene glycol, polysorbate 20, stepanol WA 100, phosphoric acid, purified water, strawberry flavor

Warnings: KEEP OUT OF REACH OF CHILDREN

Avoid spraying toward open flame. Store at room temperature. Do not expose to excessive heat over 40 degrees C or 104 degrees F. Contents under pressure. Do not puncture and incinerate.

Do not use if seal is broken.

Rx

Manufactured in Canada for

AR Medicom Inc
 Montreal, Canada, H8T 3J8
 Questions 1-800-361-2862 or www.medicom.com
 UPC 686864008644
 Item code 10037-ST
 Rev 03US

Préparation topique anti-carie.

Utilisations (pour usage professionnel seulement) :

- Utiliser après une application prophylactique complète.
- Avant d'utiliser, agiter vigoureusement le flacon, puis inverser l'embout de l'applicateur à 180° et l'insérer jusqu'au fond du (des) plateau(x).
 - Note : remplir le(s) plateau(x) au ¼ pour permettre à la mousse de gonfler.
- Insérer le(s) plateau(x) dans la bouche et demander au patient de tenir les dents légèrement serrées pendant 1 minute ou jusqu'à un maximum de 4 minutes.
- Retirer le(s) plateau(x) et cracher tout surplus.
- Recommander au patient d'éviter de manger, de boire et de se rincer la bouche 30 minutes suivant l'application.

130 applications

Ingrédients médicinaux :
 ions fluorure 1.23% p/p (1.76% fluorure de sodium et acide hydrofluorique 1.04%).

Mises en garde :
GARDER HORS DE LA PORTÉE DES ENFANTS.
 Éviter de vaporiser en direction d'une flamme nue. Entreposer à la température de la pièce. Ne pas exposer à des températures supérieures à 40°C ou 104°F. Contenu sous pression. Ne pas percer le contenant ni le jeter au feu. Ne pas utiliser si le socle est brisé.

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MEDICOM®

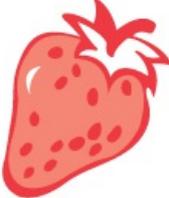
Denti-Care

DENTI-FOAM

1.76% Topical Sodium Fluoride Foam
(1.23% Fluoride Ions)

1.76% Mousse topique au fluorure de sodium
(1.23% ions fluorure)

Strawberry
Fraise



A topical anti-carries preparation.

Directions (for professional use only):

- Use after thorough prophylaxis
- To dispense, shake bottle vigorously then invert applicator 180° downward to the bottom of the tray(s)
 - Note: fill tray(s) at ¼ full to allow foam to expand
- Insert tray(s) in mouth and have patient bite down lightly for 1 minute or up to 4 minutes
- Remove tray(s) and have patient expectorate excess
- Advise patient not to eat, drink or rinse for 30 minutes after the application

130 applications

Medicinal ingredients:
 Fluoride ions 1.23% w/w (from 1.76% sodium fluoride and 1.04% hydrofluoric acid).

Non-Medicinal ingredients:
 Purified water, sodium saccharin, sodium benzoate, plasdone C30, glycerin USP, propylene glycol, polysorbate 20, stepanol WA-100, phosphoric acid and strawberry flavor.

Warnings:
KEEP OUT OF REACH OF CHILDREN.
 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 and incinerate. Do not use if seal is broken.

Manufactured in Canada for / Fabriqué aux Canada pour:
 A.R. Medicom Inc. Montreal, Canada H8T 3J8
 Questions: 1-800-361-2862 or www.medicom.com

Rx




Item Code 10037-ST

Rev03US

NDC 64778-1379-1

4.4 oz / 125g

DENTI-CARE TOPICAL SODIUM FLUORIDE STRAWBERRY

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64778-1379
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	sodium fluoride	.0176 g in 1 g

HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	HYDROFLUORIC ACID	0.010 g in 1 g
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Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64778-1379-1	125 g in 1 BOTTLE, SPRAY		

Marketing Information

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

Labeler - AR Medicom Inc (247876295)

Revised: 2/2011

AR Medicom Inc