

**DENTI-CARE TOPICAL FLUORIDE FOAM BUBBLE GUM- fluoride ions 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 Topical Fluoride Foam Bubble Gum 1.23% Fluoride Ions

Denti-Care

Denti-Foam

Topical Fluoride Foam Bubble Gum

1.23 % Fluoride Ions

4.4 oz / 125 g

NDC 64778-1373-1

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, bubble gum 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 Only

Manufactured in Canada for

AR Medicom Inc

Montreal, Canada, H8T 3J8

Questions 1-800-361-2862 or www.medicom.com
 UPC 686864008668
 Item code 10037-BG
 Rev 00

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 1/4 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 sceau est brisé.

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Item Code 10037-BG Rev00 NDC 64778-1373-1 4.4 oz / 125g

MEDICOM®

Denti-Care

DENTI-FOAM

Topical Fluoride Foam
 1.23% Fluoride Ions

Mousse topique au fluorure
 1.23% ions fluorure

Bubblegum
 Gomme ballonne



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 1/4 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 bubble gum 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 Only




DENTI-CARE TOPICAL FLUORIDE FOAM BUBBLE GUM

fluoride ions aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64778-1373
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	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64778-1373-1	125 g in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/09/2011	

Labeler - AR Medicom Inc (247876295)

Revised: 2/2011

AR Medicom Inc