DENTI-CARE TOPICAL FLUORIDE FOAM GRAPE- 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 grape 1.23% Fluoride Ions

Denti-Care

Denti-Foam

Topical Fluoride Foam Grape

1.23 % Fluoride Ions

4.4 oz / 125 g

NDC 64778-1375-1

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, grape 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 Préparation topique anti-carie.

Utilisations (pour usage professionnel seulement):

- 1. Utiliser après une application prophylactique complète.
- 2. 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.
- 4. Retirer le(s) plateau(x) et cracher tout
- 5. 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. Entreposeràla température de la pièce. Ne pas exposer à des températures supéri-eures à 40°C ou 104°F. Contenu sous pression. Ne pas percer le contenant ni le jeterau feu. Ne pas utiliser si le sceau est brisé.

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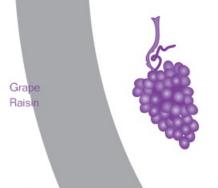
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Rev00



Topical Fluoride Foam 1.23% Fluoride Ions

Mousse topique au fluorure 1.23% ions fluorure



NDC 64778-1375-1 4.4 oz / 125g A topical anti-caries preparation.

Directions (for professional use only): 1. 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 expecto-
- rate 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:

Purified water, sodium saccharin, sodium benzoate, plasdone C30, glycerin USP, propylene glycol, polysorbate 20, stepanol WA-100, phosphoric acid and grape flavor.

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 GRAPE

fluoride ions aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64778-1375
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	so dium fluo ride	.0176 g in 1 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	HYDROFLUORIC ACID	0.010 g in 1 g

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

	Packaging	ckaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:64778-1375-1	125 g in 1 BOTTLE, SPRAY			

Marketing Infor	arketing 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