DENTI-CARE DENTI-RINSE NEUTRAL SODIUM FLUORIDE ORAL RINSE- sodium fluoride liquid AMD Medicom

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.

10044-M Mint Rinse DentiCare Pro-Rinse 2 % Neutral Sodium Fluoride Oral Rinse

General Information

AMD Medicom Inc.

DentiCare Pro-Rinse

2% Neutral Sodium Fluoride Oral Rinse Mint

1.9 L / 64 fl oz

NDC 64778-0446-1

NPN 80008542

Item code 10044-M

Indications and Directions

Indications: Topical anti-carie solution. Neutral pH is safe for patients with crowns and restorations.

Directions: Dispense 10mL of solution into a measuring cup. Instruct patient to rinse vigorously for 60 seconds, around and in between teeth, then expectorate. For maximum benefit, repeat the rinse procedure with an additional 10mL.

Advise patient not to eat, drink or rinse for 30 minutes after application.

Pro-Rinse solution may also be applied with a cotton tip applicator to teeth isolated with cotton rolls

Non-Medicinal Ingredients

Citric acid, potassium sorbate, purified water, sorbitol, sucralose, blue 1, yellow 5, peppermint flavour, sodium hydroxide

Warnings

KEEP OUT OF REACH OF CHILDREN. For professional use only.

Not recommended for use by children under 6 years of age.

Do not swallow.

Store at room temperature. Do not expose to excessive heat over 40°C or 104°F .

Do not use if seal is broken.

Contact Information

Rx Only in US

Made in USA for AMD Medicom Inc. 2555 Chemin de l'Aviation, Pointe-Claire, Quebec, Canada H9P 2Z2

Questions: 1-800-361-2862

www.medicom.com

Principal Display Panel



DENTI-CARE DENTI-RINSE NEUTRAL SODIUM FLUORIDE ORAL RINSE

sodium fluoride liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64778-0446
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.02g in $1mL$

Product Characteristics			
Color	green	Score	

Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64778-0446-3	12 in 1 CASE	12/0 1/20 17	
1	NDC:64778-0446- 1	1900 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/01/2001	

Labeler - AMD Medicom (256880576)

Registrant - AMD Medicom (256880576)

Revised: 1/2021 AMD Medicom