

NAFRINSE UNIT DOSE MINT FLAVOR- sodium fluoride and hydrofluoric acid solution
NAFRINSE UNIT DOSE BUBBLE GUM- sodium fluoride and hydrofluoric acid solution
NAFRINSE UNIT DOSE VERRY BERRY- sodium fluoride and hydrofluoric acid solution
Young Dental Manufacturing Co 1, LLC.

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](#).

Active Ingredients

Sodium Fluoride

Inactives

Saccharin Sodium, Potassium Sorbate, Citric Acid, Flavoring
Dye (Only present in Mint and Very Berry flavors)

Purpose

Prevention of dental caries.

Warning:

a) Do not swallow b) Do not eat, drink or rinse with water for 30 minutes after use. c) Instruct children under 12 years of age in the use of the product and in good brushing and rinsing habits to minimize swallowing d) Not recommended for use in children younger than 6 years of age.

Dosage and Administration:

DIRECTIONS FOR USE: {Best Results • Use Early Morning)

1. Each pupil receives one cup and one napkin. 2. Have the pupils remove the lids from the cups. 3. Have the pupils empty the contents of the cup into their mouths and swish thoroughly for one minute. 4. **HOLD CUP AGAINST THE MOUTH.** Spit solution back into the cup. 5. Have the pupils wipe their mouths with the napkin; then stuff the napkin slowly into the cup to absorb the solution. 6. Discard the cup with the napkin into the provided trash bag. a) Do not swallow b) Do not eat, drink or rinse with water for 30 minutes after use. c) Instruct children under 12 years of age in the use of the product and in good brushing and rinsing habits to minimize swallowing d) Not recommended for use in children younger than 6 years of age. **ADDITIONAL INSTRUCTIONS/IMPORTANT:** In order to avoid spillage of the solution from the cup, the children must be instructed to do the following: 1) When spitting the fluoride solution from the mouth back into the cup, the children must hold the cup close to the mouth, and spit slowly into the cup. 2) The napkins must be stuffed into the cups very slowly in order to avoid spillage.

Keep out of reach of children

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Product Label

NPN 80024502
BUBBLE GUM (DYE FREE)
NAFRINSE
FLUORIDE MOUTHRINSE
Contains: 28 mg of Sodium Fluoride
in a specially prepared aqueous vehicle.
FOR TOPICAL USE ONLY.
Rinse for 1 minute and SPIT OUT.
DO NOT SWALLOW.
Caution: Federal (USA) law prohibits
dispensing without prescription.
1

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657569

LOT EXP.

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657568

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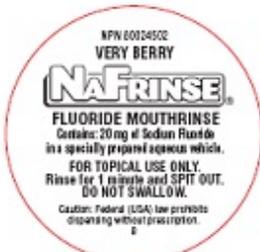
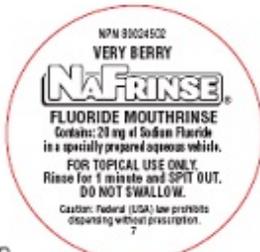
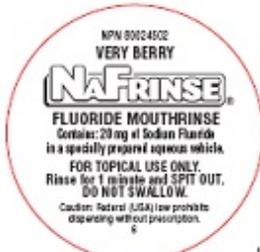
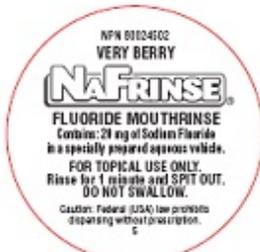
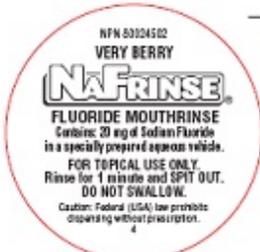
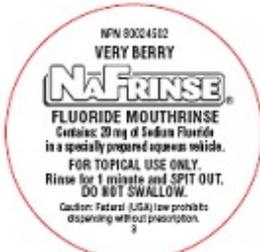
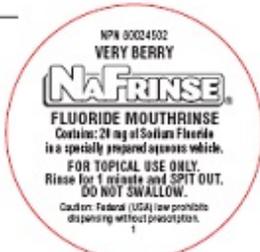
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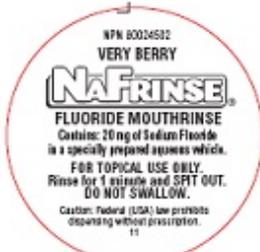
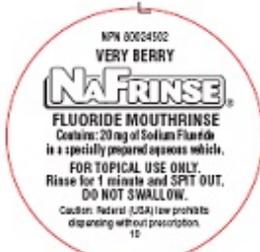
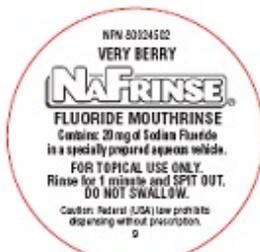
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12



657567

LOT EXP.



NAFRINSE UNIT DOSE MINT FLAVOR

sodium fluoride and hydrofluoric acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT (mint)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8002-01	10 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		08/24/2017		

NAFRINSE UNIT DOSE BUBBLE GUM				
sodium fluoride and hydrofluoric acid solution				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8003	
Route of Administration	DENTAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)		Fluoride Ion	2 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
Potassium Sorbate (UNII: 1VPU26JZZ4)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	BUBBLE GUM (bubble gum)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:0273-8003-01	10 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		08/24/2017		

NAFRINSE UNIT DOSE BUBBLE GUM
sodium fluoride and hydrofluoric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8004
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (bubble gum)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8004-01	5 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2017	

NAFRINSE UNIT DOSE VERRY BERRY

sodium fluoride and hydrofluoric acid solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8005
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY (very berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8005-01	10 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2017	

Labeler - Young Dental Manufacturing Co 1, LLC. (006309355)

Registrant - Medical Products Laboratories, Inc (002290302)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc		002290302	manufacture(0273-8002, 0273-8003, 0273-8004, 0273-8005)

