NAFRINSE UNIT DOSE FLUORIDE- sodium fluoride 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.

Inactives

Saccharin Sodium, Potassium Sorbate, Citric Acid, Flavoring Dye

Warning:

For Topical use only.

Federal (USA) law prohibits dispensing without prescription

Directions

Rinse for 1 minute and spit out. Do not swallow.



NAFRINSE UNIT DOSE FLUORIDE

sodium fluoride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	20 mg in 10 mL	

Inactive Ingredients		
Ingredient Name	Strength	
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
Potassium Sorbate (UNII: 1VPU26JZZ4)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (grape)	Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0273-8001-01	10 mL in 1 CUP; Type 0: Not a Combination Product	09/25/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/24/2017	

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(0273-8001)	