NAFRINSE PACKETS MINT- sodium fluoride powder 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:

This Packet contains sodium fluoride powder, contents poisonous if swallowed. keep away from children. Store in a dry place at controlled room temperature. For professional use only.

DO NOT SWALLOW

MISSUSE If child swallows dispensed amount of mouth rinse in a cup:

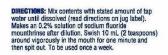
1. Do not panic -this amount should not hurt the child

2. In rare cases the child may feel slightly nauseous.

The child may have a serving of milk or ice cream to relieve the nausea. EMERGENCY TREATMENT If a child swallows more than one dispensed amount in a cup or powder contents of the fluoride mouth rinse packet call the Poison Control Center at 800-222-1222

Directions

Mix contents with stated amount of tap water until dissolved (read directions on jug label) Makes an 0.2 % solution of sodium fluoride mouthrinse aftert dilution. Swish 10 ml (2 teaspoons) around vigorously in the mouth for one minute and then spit out. To be used once a week.



DIRECTIONS: Mix contents with stated amount of tap water until dissolved (read directions on jug label). Makes an 0.2% solution of solutim fluoride mounthrinse after dilution. Swish 10 mL (2 taspoons) around vigorously in the mount for one minute and then spit out. To be used once a week. DIRECTIONS: Mix contents with stated amount of tap water until dissolved (read directions on jug label). Makes an 0.2% solution of solution fluoride mounthrinse after dilution. Swish 10 m. (2 teaspoons) around vigorously in the mouth for one minute and then splt out. To be used once a week.

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TEAR RESISTANT PACKET



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sodium fluoride powder					
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	PRESCRIPTION DRUG Item Code (Source)		NDC:0273-8017	
Route of Administration	DENTAL				
Active Ingredient/Active M	Ioiety				
	Ingredient Name Basis of S		Basis of Stre	ength	Strength
Sodium Fluoride (UNII: 8ZYQ1474	4W7) (Fluoride Ion - UNII:Q80VPU408O)		Fluoride Ion		1g in 1g
Inactive Ingredients	Tur you d'and Name -			<u>C</u> t	
	Ingredient Name			St	rength
SACCHARIN SODIUM (UNII: SB82	ZUX40TY)			Str	rength
Inactive Ingredients SACCHARIN SODIUM (UNII: SB87 Potassium Sorbate (UNII: 1VPU26 ANHYDROUS CITRIC ACID (UNII	ZUX40TY) JZZ4)			St	rength
SACCHARIN SODIUM (UNII: SB82 Potassium Sorbate (UNII: 1VPU26	ZUX40TY) JZZ4)			Sti	rength
SACCHARIN SODIUM (UNII: SB8/ Potassium Sorbate (UNII: 1VPU26 ANHYDROUS CITRIC ACID (UNII	ZUX40TY) JZZ4)			St	rength
SACCHARIN SODIUM (UNII: SB82 Potassium Sorbate (UNII: 1VPU26 ANHYDROUS CITRIC ACID (UNII Product Characteristics	ZUX40TY) JZZ4) : XF417D3PSL)	ore		Str	rength
SACCHARIN SODIUM (UNII: SB82 Potassium Sorbate (UNII: 1VPU26 ANHYDROUS CITRIC ACID (UNII Product Characteristics Color	ZUX40TY) JZZ4) : XF417D3PSL)			St	rength
SACCHARIN SODIUM (UNII: SB82 Potassium Sorbate (UNII: 1VPU26 ANHYDROUS CITRIC ACID (UNII Product Characteristics Color Shape	ZUX40TY) JZZ4) : XF417D3PSL) Sc Siz			St	rength

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:0273-8017-03	50 in 1 PACKAGE	09/21/2017				
3 g in 1 PACKET; Type 0: Not a Combination Product						
Marketing Inf	ormation					
Marketing Inf						
Marketing Info		Marketing Start Date	Marketing End Date			

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(0273-8017)

Revised: 12/2018

Young Dental Manufacturing Co 1, LLC.