NAFRINSE PACKETS MINT- sodium fluoride powder
Young Dental Manufacturing I, 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 (Only present in Mint and Very Berry flavors)

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:

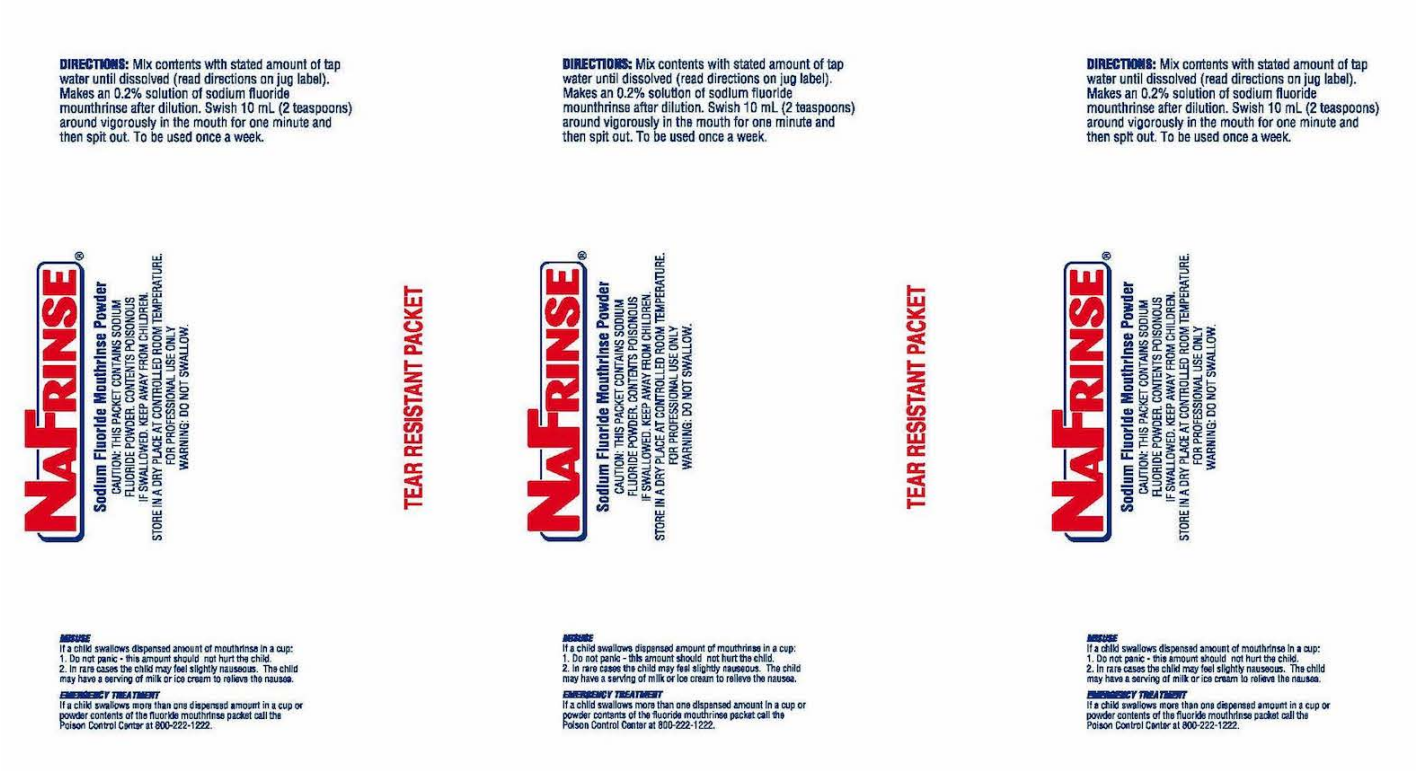
1. Do not panic -this amount should not hurt the child

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 mouth rinse 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.



NAFRINSE PACKETS MINT

sodium fluoride powder

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0273-8013
Route of Administration	DENTAL		

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

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:0273-8013-02	50 in 1 PACKAGE	09/21/2017	
1		2 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/21/2017	

Labeler - Young Dental Manufacturing I, LLC (006309355)

Registrant - Young Dental Manufacturing I, LLC (006309355)

Establishment

Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(0273-8013)

Revised: 12/2018 Young Dental Manufacturing I, LLC