

NAFRINSE PACKETS VERY BERRY- 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

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:

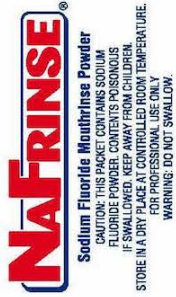
1. Do not panic -this amount should not hurt the child
2. In rare cases the child may feel slightly nauseous.

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.

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TEAR RESISTANT PACKET



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ABUSE
If a child swallows dispensed amount of mouthrinse in a cup:
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EMERGENCY TREATMENT
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NAFRINSE PACKETS VERY BERRY

sodium fluoride powder

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8012
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	BERRY (very berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8012-02	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(0273-8012)

Revised: 12/2018

Young Dental Manufacturing I, LLC