

**NAFRINSE PACKETS GRAPE- 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](#).*

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**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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## NAFRINSE PACKETS GRAPE

sodium fluoride powder

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0273-8020
<b>Route of Administration</b>	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

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (grape)	<b>Imprint Code</b>	
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8020-03	50 in 1 PACKAGE	09/21/2017	
1		3 g in 1 PACKET; Type 0: Not a Combination Product		

  

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

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

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc.		002290302	manufacture(0273-8020)

Revised: 12/2018

Young Dental Manufacturing Co 1, LLC.