

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

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**Convenience KIT -20 pack of Nafrinse packets, a polyethylene jug, dispenser pump, plastic cups, paper napkins, and trash bag with ties**

**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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**NAFRINSE**<sup>®</sup>  
Sodium Fluoride Mouthrinse Powder  
CAUTION: 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.  
WARNING: DO NOT SWALLOW.

TEAR RESISTANT PACKET

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**ABUSE**  
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**USE 3 g OF SODIUM FLUORIDE  
1500 mL WATER**

**WATERINSE**

**SODIUM FLUORIDE MOUTHRINSE (**

**USE 2 g OF SODIUM FLUORIDE  
1000 mL WATER**

**DIRECTIONS:**

1. Fill container with tap water to appropriate a
2. Empty packet into container.
3. Replace cap and shake well.
4. Remove cap, insert pump carefully and push gently several times to prime.
5. Depress pump fully one time to dispense one amount of mouthrinse for each child.

**USING INSTRUCTIONS:**

Swish solution vigorously around mouth for one minute, then

**USE 1 g OF SODIUM FLUORIDE  
500 mL WATER**

Discard any mixed solution after 3 weeks.

**CAUTION:** Do not swallow. Store out of reach of c

# NAFRINSE PACKETSKIT GRAPE

sodium fluoride powder

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0273-8009
<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)	
ANHYDRO US 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>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8009-02	20 in 1 KIT	09/25/2017	
1	NDC:0273-8009-01	3 g in 1 PACKET; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/25/2017	

**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(0273-8009)

