

NAFRINSE PACKETSKIT BUBBLE GUM- 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](#).

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[®]
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.

ADDITIONAL 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 BUBBLE GUM

sodium fluoride powder

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8008
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)	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (bubble gum)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-8008-02	20 in 1 KIT	09/25/2017	
1	NDC:0273-8008-01	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(0273-8008)

