NAFRINSE UNIT DOSE MINT FLAVOR- sodium fluoride and hydrofluoric acid solution NAFRINSE UNIT DOSE BUBBLE GUM- sodium fluoride and hydrofluoric acid solution NAFRINSE UNIT DOSE VERRY BERRY- sodium fluoride and hydrofluoric acid solution 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.

Active Ingredients

Sodium Fluoride

Inactives

Saccharin Sodium, Potassium Sorbate, Citric Acid, Flavoring Dye (Only present in Mint and Very Berry flavors)

Purpose

Prevention of dental caries.

Warning:

a) Do not swallow b) Do not eat, drink or rinse with water for 30 minutes after use. c) Instruct children under 12 years of age in the use of the product and in good brushing and rinsing habits to minimize swallowing d) Not recommended for use in children younger than 6 years of age.

Dosage and Administration:

DIRECTIONS FOR USE: {Best Results • Use Early Morning}

1. Each pupil receives one cup and one napkin. 2. Have the pupils remove the lids from the cups. 3. Have the pupils empty the contents of the cup into their mouths and swish thoroughly for one minute. 4. HOLD CUP AGAINST THE MOUTH. Spit solution back into the cup. 5. Have the pupils wipe their mouths with the napkin; then stuff the napkin slowly into the cup to absorb the solution. 6. Discard the cup with the napkin into the provided trash bag. a) Do not swallow b) Do not eat, drink or rinse with water for 30 minutes after use. c) Instruct children under 12 years of age in the use of the product and in good brushing and rinsing habits to minimize swallowing d) Not recommended for use in children younger than 6 years of age. ADDITIONAL INSTRUCTIONS/IMPORTANT: In order to avoid spillage of the solution from the cup, the children must be instructed to do the following: 1) When spitting the fluoride solution from the mouth back into the cup, the children must hold the cup close to the mouth, and spit slowly into the cup. 2) The napkins must be stuffed into the cups very slowly in order to avoid spillage.

Keep out of reach of children

Keep out of reach of children

Product Label



Caution: Federal (16A) (aw prehibits dispensing without prescription.

NPN 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE
Cutains: 21 mg of Sedum Floorite
in a specially prepared aqueses which.
FOR TOPPICAL USE DULY.
Rinse for 4 minute and SPIT OUT.
DO NOT SWALLOW. Caution: Federal (USA) law prohibits disparsing without protectpilen.

MPW 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Cutains 20 mg of 3 rdun fluoride in a specially prepared equature webide. FOR TOPICAL USE ONLY, Rinne for 1 minute and 3 PIT OUT. DO NOT SWALLOW.

MPN 80024502 BUBBLE GUM (DYE FREE) No Carried FLUORIDE MOUTHRINSE Combine 20 mg of Sediem Fluoride in a specially propered aquesus vehicle. FOR TOPICAL USE ONLY.
Rinse for 1 minute and SPIT OUT.
DO NOT SWALLOW. Caution: Federal (USA) law prohibits disputating without proceedation.

NEW 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Contains: 21 mg of Sediam Flooride in a specially prepared a queeux rehide. FOR TOPICAL USE ONLY. use for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Federal (USA) two prohibits disparating without prescription.

MPW 80024502

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Contine Mooth Revide in a specially propered agreem whice. FOR TOPICAL USE ONLY. Rinso for 1 minute and SPIT OUT. DO NOT SWALLOW.

Carrion: Federal (USA) law prohibits departeing without precoription.

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NPW 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Catains 20 mg of Sedum Provide in a specially prepared reports whitele. FOR TOPPCAL USE ONLY. DO NOT SWALLOW.

NPW 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Certains: 20 mg of Sedum Rhorido in a specially prepared agreeous which. FOR TOPICAL USE ONLY. Brisse for 1 minutes and SPIT OUT. DO NOT SWALLOW.

Caution: Fadoral (USA) law prohibits dispensing without prescription.

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979 80024500 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Contains: 20 mg of Sodiem Recorde in a specially prepared agreeous which. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Futural (USA) law prohibits dispunsing without prescription.

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NPN 80024502

BUBBLE GUM (DYE FREE)

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FLUORIDE MOUTHRINSE PLOONIDE MOOTHHINSE Contains: 20 ng of Sedium Fluoride in a specially prepared aqueens which. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Federal (USA) law prehists dispersing without preceiption.

NPN 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Coutsin: 20 mg of Softm Fluoride is a specially propared agreese which. FOR TOPICAL USE ONLY. Risse for 1 minute and SPIT OUT. DO NOT SWALLOW.

Cauton: Federal (USA) law prohibits dispensing without prescription.

NPN 80024502 BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE Cotain: 20 mg of Sodian Fluoride in a spicially prejend agreeous which. For TOPICAL USE ONLY. Rinses for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Federal (II SA) law prohibits disputeing without precoription.

BUBBLE GUM (DYE FREE) FLUORIDE MOUTHRINSE

Contain: 18 ng of Solium Floodée is a specially ympomed aqueens which, FOR TOPICAL USE ONLY. Rinne for 1 minute and SPIT OUT, DO NOT SWALLOW.

Caution: Federal (USA) law prohibits dispensing without prescription.

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Contains: 10 mg of Sedem Flueride in a specially prepared agreem vehicle. FOR TOPICAL USE ONLY. Rimes for 1 minutes and SPIT OUT. DO NOT SWALLOW.

Caution Federal (USA) law prohibits disparsing without processed on.

BUBBLE GUM (DYE FREE)

Ca Faires FLUORIDE MOUTHRINSE

Cottain: 18 mg af Sodiam Flaui ée is a specially prepared agreem white. FOR TOPICAL USE ONLY. Rinne he 1 minute and SPIT OUT. DO NOT SWALLOW. Caution: Federal (USA) law prohibits dispensing without prescription.

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Centains: 18 mg et Sedom Humide in a specially prepared agreem vehicle. FOR TOPICAL USE ONLY. Rince for 1 minute and SPIT OUT. DO NOT SWALLOW. Cautian: Federal (USA) law prohibits dispensing without practipities.

BUBBLE GUM (DYE FREE) R.Gaixea

FLUORIDE MOUTHRINSE

Centains: 10 mg el Sedium Rippide in a specially prepanel agreeux rehide. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Federal (USA) law profession dispensing without prescription.

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Cotsie: 10 mg of Solim Fluoride in a specially prejand aquesus vehide. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. 00 NOT SWALLOW.

Content Redwal (USA) law prohibits dispensing without preceiption.

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Corbins: 18 mg of Sodium Flouride in a specially prepared agreeus vehicle. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW.

Coultern Redward (USA) law pro-Notes dispursing without precomption.

BUBBLE GUM (DYE FREE) FLUORIDE MOUTHRINSE

Contains: 10 mg el Sadium Fluride in a specially prepared agrecus rehide. FOR TOPICAL USE ONLY. Rinse lie 1 minute and SPIT OUT. DO NOT SWALLOW.

Castian: Federal (USA) are prohibite dispensing without practips in.

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BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Certains: 18 mg et Sedom Rusride in a specially graphed agnesis rehide. FOR TOPICAL USE ONLY. Rinne for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Federal (USA) law profession dispensing without prescription.

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L BUBBLE GUM (DYE FREE)

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FLUORIDE MOUTHRINSE

Cottsis: 18 ng of Sodium Flouride in a specially prepared agreeus whide. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW. Caudion: Redwall (USA) law prohibits dispursing without precorption. 10

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHRINSE

Contains: 10 mg et Sodium Flumide in a spedally prejected agrecus tehiolo. FOR TOPICAL USE ONLY. Finne lie 1 minute and SPIT OUT, DO NOT SWALLOW. Coston: Federal (USA) law prohibits dispensing without prescription.

BUBBLE GUM (DYE FREE)

FLUORIDE MOUTHINSE

Contains: 10 mg of Sodium Fluride in a specially prepared agreems whide. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW. Cardon: Reducal (USA) law prohibits dispursing without precorption. 12













FLUORIDE MOUTHRINSE Combins: 21 mg of Sedim Fluoride in a specially prepared acquicut whilede. For TOPICAL USE ONLY. Rinse for 1 minute and SMT OUT, DO NOT SWALLOW. Caution: Federal (USA) law prohibits dispensing without prescription.

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FLUORIDE MOUTHRINSE Contains: 20 mg of Sedum Pluoride in a specially proposed agreeous whicle. For TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT, DO NOT SWALLOW. Caution: Federal (USA) law prohibits departing without prescription.

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LOT EXP. NPN 80024502 MINT EBILLER

FLUORIDE MOUTHRINSE Cottain: 20 mg of Sodum Ruoride in a specially project deposits which, FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW.

Caution: Federal (USA) law prohibits dispending without prescription.

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Manes. FLUORIDE MOUTHRINSE Cotains: 20 mg of Sadour Ausride in a specially proposed agreeous whick. For TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT, DO NOT SWALLOW.

NPN 80024502

Caution: Federal (USA) law prohibits dispunsing without prescription.

NPN 80024502 MINT

FLUORIDE MOUTHRINSE Contains: 20 mg of Sadium Rueride in a specially prepared aqueous vehide. POR TOPICAL USE ONLY.
Rinse for 1 minute and SPIT OUT.
DO NOT SWALLOW.
Cautor Reduct (USA) law prohibits
dispensing without prescription.

NPN 80024502 MINT EBXLET FLUORIDE MOUTHRINSE
Cottains: 30 ng of Seilum Ruende
is a specially prepared aqueous which,
FOR TOPICAL USE DULY.
Rinse for 1 minute and SPT OUT.
DO NOT SWALLOW.
Cactor. Natural (USA) interprisints
depareing without prescription.

NPW 80024502 MINT FLUORIDE MOUTHRINSE Contains: 20 mg of Sodium Flooride in a specially prepared squeous vehicle. FOR TOPICAL USE ONLY. Rinse for 1 minute and SPIT OUT. DO NOT SWALLOW.

MINT EBXLLIK FLUORIDE MOUTHRINSE Contains: 20 mg of Sodium Ruoride in a specially prepared aqueous which. the specially prepared agreeds which.
FOR TOPICAL USE ONLY.
Rinse for 1 minute and SPIT OUT.
DO NOT SWALLOW.
Caution Federal (SEA) law prohibits
disparating without prescription.
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NPN 80024502























NFW 80035652
VERY BERRY

FLUORIDE MOUTHRINSE
Cartaine: 20 mg ef Sedua Ruadé
in specially prepara Segentur Michol
FER TOPICAL USE ONLY.
Rinse For 1 minute and SPIT OUT,
DO NOT SWALLOW.
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NAFRINSE UNIT DOSE MINT FLAVOR

657567

sodium fluoride and hydrofluoric acid solution

Product Information

 Product Type
 HUMAN PRESCRIPTION DRUG
 Item Code (Source)
 NDC:0273-8002

 Route of Administration
 DENTAL

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EXP.

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)				
Potassium Sorbate (UNII: 1VPU26JZZ4)				
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (mint)	Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0273-8002-01	10 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2017	

NAFRINSE UNIT DOSE BUBBLE GUM

sodium fluoride and hydrofluoric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
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:0273-8003-01	10 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	
Marketing Info	rmation		
Marketing Info	rmation		
Marketing Info		Marketing Start Date	Marketing End Date

NAFRINSE UNIT DOSE BUBBLE GUM

sodium fluoride and hydrofluoric acid solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-8004
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
Potassium Sorbate (UNII: 1VPU26JZZ4)			
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)			

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

l	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:0273-8004-01	5 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2017	

NAFRINSE UNIT DOSE VERRY BERRY

sodium fluoride and hydrofluoric acid solution

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:0273-8005

Route of Administration DENTAL

Active Ingredient/Active Moiety

ı	,		
ı	Ingredient Name	Basis of Strength	Strength
ı	Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2 mg in 1 mL

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	BERRY (very berry)	Imprint Code	
Contains			

Packaging

1	0 0			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:0273-8005-01	10 mL in 1 CUP; Type 0: Not a Combination Product	08/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2017	

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

Registrant - Medical Products Laboratories, Inc (002290302)

Establishment

Littonisment			
Name	Address	ID/FEI	Business Operations
Medical Products Laboratories, Inc		002290302	manufacture(0273-8002, 0273-8003, 0273-8004, 0273-8005)