TREATMENT RINSE APPLE- anticaries rinse TREATMENT RINSE MINT- anticaries rinse DENTAL ALLIANCE HOLDINGS LLC

Treatment Rinse

Active ingredients:

Sodium Fluoride 0.05% when mixed with part B

Purpose:

Anticavity

Use:

Aids in the prevention of dental caries (cavities)

Warnings:

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away. If you experience any unusual symptoms, stop use and contact your dentist.

Warnings:

Keep out of reach of children.

Directions:

Do not use before mixing with Part B. Adults and children 6 years of age and older: Use once daily after brushing. Shake each bottle before use. Using the measuring cup, combine 5 mL of component A with 5 mL of component B (10 mL, total). Vigorously swish the combined 10 mL of rinse between teeth for one minute, then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or physician. Do not dilute. Do not use either component alone. Store below 30 degrees C (86 degrees F). Do not freeze.

Inactive ingredients:

Menthol, Natural Flavors, Polysorbate 20, Sodium Benzoate, Sodium Hydroxide, Sodium Hypochlorite, Water, Xylitol.

Treatment Rinse Mint and Apple enclosure and carton labels:







TREATMENT RINSE

ANTI-CAVITY
CONCENTRATED SOLUTION

В

Mix 1:1 with component A Do not rinse with component B alone

> IMPORTANT: Read directions for proper use

5.9 fl oz (175.5 ml)

For your protection, this product contains a seal under the cap. Recommended to use within 3 months after opening.



U.S PATENTS NO. 9,427,384 and 10,143,633

Drug Facts

Warnings

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away. If you experience any unusual symptoms, stop use and contact your dentist.

Directions Do not use before mixing with Part A.

■ Adults and children 6 years of age and older: Use once daily after brushing. Shake each bottle before use. Using the measuring cup, combine 5 mL of component A with 5 mL of component B (10 mL, total). Vigorously swish the combined 10 mL of rinse between teeth for one minute, then spit out. Do not swallow the rinse. Do not eat or drink for 30 minutes after rinsing. Instruct children under 12 years of age in good rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

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Inactive ingredients Sodium Hydroxide, Sodium Hypochlorite, Water

Questions or comments? 800.503.0625

carifree.com

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TREATMENT RINSE

ANTI-CAVITY CONCENTRATED SOLUTION





Mix 1:1 with component B

Do not rinse with component A alone

IMPORTANT: Read directions for proper use

5.9 fl oz (175.5 ml)

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U.S PATENTS NO. 9,427,384 and 10,143,633

Drug Facts

Active ingredients

Purpose

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Inactive ingredients Menthol, Natural Flavors, Polysorbate 20, Sodium Benzoate, Water, Xylitol

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TREATMENT RINSE

ANTI-CAVITY
CONCENTRATED SOLUTION





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Inactive ingredients Natural Flavors, Sodium Benzoate, Water, Xylitol

Questions or comments? 800.503.0625

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TREATMENT RINSE APPLE

anticaries rinse

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:61578-315

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION 226 ug in 1 mL

Inactive Ingredients Ingredient Name Strength SODIUM BENZOATE (UNII: OJ245FE5EU) WATER (UNII: 059QF0KO0R) XYLITOL (UNII: VCQ006KQ1E) SODIUM HYDROXIDE (UNII: 55X04QC32I) SODIUM HYPOCHLORITE (UNII: DY38VHM50D)

Product Characteristics			
Color	white (hazy)	Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

ı	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:61578-315-01	2 in 1 PACKAGE	05/10/2022			
	1	175.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	05/10/2022		

TREATMENT RINSE MINT

anticaries rinse

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61578-314	
Route of Administration	DENTAL			

Active Ingredient/Active Moiety Ingredient Name

Ingredient Name

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)

FLUORIDE ION

226 ug in 1 mL

Inactive Ingredients

Ingredient Name
Strength

MENTHOL (UNII: L7T10EIP3A)

POLYSORBATE 20 (UNII: 7T1F30V5YH)

SODIUM BENZOATE (UNII: OJ245FE5EU)

WATER (UNII: 059QF0KO0R)

XYLITOL (UNII: VCQ006KQ1E)

SODIUM HYDROXIDE (UNII: 55X04QC32I)

SODIUM HYPOCHLORITE (UNII: DY38VHM50D)

Product Characteristics

Color	white (hazy)	Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

l	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
l		NDC:61578- 314-01	2 in 1 PACKAGE	05/10/2022		
	1		175.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

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OTC Monograph Drug	M021	05/10/2022		

Labeler - DENTAL ALLIANCE HOLDINGS LLC (195544965)

Registrant - DENTAL ALLIANCE HOLDINGS LLC (195544965)

Establishment				
Name	Address	ID/FEI	Business Operations	
DENTAL ALLIANCE HOLDINGS LLC		195544965	manufacture(61578-314, 61578-315)	

Revised: 1/2024 DENTAL ALLIANCE HOLDINGS LLC