

CTX3 RINSE MINT- anticaries rinse
CTX3 RINSE GRAPE- anticaries rinse
CTX3 RINSE CITRUS- anticaries rinse
Dental Alliance Holdings LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Maintenance Rinse

Active ingredients:

Sodium Fluoride 0.05%

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:

Adults and children 6 years of age and older: Use once daily after brushing your teeth with toothpaste. Vigorously swish 10mL 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. Store below 30 degrees C (86 degrees F). Do not freeze.

Inactive ingredients:

Menthol (Mint only), Natural Flavors (Mint only), Natural and Artificial Flavors (Citrus and

Grape only), Polysorbate 20, Potassium Sorbate, Sodium Benzoate, Sodium Bicarbonate, Water, Xylitol

CTx3R Mint, Citrus, and Grape enclosure labels:



MINT

Anticavity rinse

2 FL OZ (60 mL)

IMPORTANT: Read directions for proper use

Questions or comments?

800.503.0625

www.carifree.com

CariFree and pH+ are registered trademarks of Oral BioTech
Manufactured by Oral BioTech
Albany, Oregon 97321 USA

For your protection, this product contains a seal under the cap.



PATENTS PENDING

Drug Facts

Active ingredients:

Sodium Fluoride 0.05%

Purpose:

Anticavity

Use: Aids in the prevention of dental caries (cavities)

Warnings:

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Directions: Adults and children 6 years of age and older:

Use once daily after brushing your teeth with toothpaste. Vigorously swish 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. Store below 30 degrees C (86 degrees F). Do not freeze.

Inactive ingredients: Menthol, Natural Flavors, Polysorbate 20, Potassium Sorbate, Sodium Benzoate, Sodium Bicarbonate, Water, Xylitol

CariFree®

CTx3™ Rinse



- pH Neutralization
- Xylitol
- Fluoride

CITRUS
Anticavity rinse
16 FL OZ (473 mL)

IMPORTANT: Read directions for proper use

www.carifree.com



For your protection, this product contains a seal under the cap.

U.S. PATENT NO. 9,427,384

Drug Facts

Active Ingredients:

Sodium Fluoride 0.05%

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.

Directions: Adults and children 6 years of age and older: Use once daily after brushing your teeth with toothpaste. Vigorously swish 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. Store below 30 degrees C (86 degrees F). Do not freeze.

Inactive Ingredients: Natural and Artificial Flavors, Polysorbate 20, Potassium Sorbate, Sodium Benzoate, Sodium Bicarbonate, Water, Xylitol

Questions or comments? 800.503.0625

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CariFree®

CTx3™ Rinse



- pH Neutralization
- Xylitol
- Fluoride

GRAPE
Anticavity rinse
16 FL OZ (473 mL)

IMPORTANT: Read directions for proper use

www.carifree.com



For your protection, this product contains a seal under the cap.

U.S. PATENT NO. 9,427,384

Drug Facts

Active ingredients:

Sodium Fluoride 0.05%

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.

Directions:

Adults and children 6 years of age and older: Use once daily after brushing your teeth with toothpaste. Vigorously swish 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. Store below 30 degrees C (86 degrees F). Do not freeze.

Inactive ingredients: Artificial Flavors, Polysorbate 20, Potassium Sorbate, Sodium Benzoate, Sodium Bicarbonate, Water, Xylitol

Questions or comments? 800.503.0625

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CariFree®

CTx3TM Rinse



- pH Neutralization
- Xylitol
- Fluoride

MINT
Anticavity rinse
16 FL OZ (473 mL)

IMPORTANT: Read directions for proper use

www.carifree.com



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U.S. PATENT NO. 9,427,384

Drug Facts

Active Ingredients:

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Purpose:

Anticavity

Use: Aids in the prevention of dental caries (cavities)

Warnings:

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Inactive Ingredients: Menthol, Natural Flavors, Polysorbate 20, Potassium Sorbate, Sodium Benzoate, Sodium Bicarbonate, Water, Xylitol

Questions or comments? 800.503.0625

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CTX3 RINSE MINT

anticaries rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61578-301
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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)	

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-301-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2012	09/30/2022
2	NDC:61578-301-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2012	09/30/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2012	09/30/2022

CTX3 RINSE GRAPE

anticaries rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61578-303
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	226 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

WATER (UNII: 059QF0KO0R)

XYLITOL (UNII: VCQ006KQ1E)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-303-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2012	
2	NDC:61578-303-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2012	11/30/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2012	

CTX3 RINSE CITRUS

antiararies rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61578-302
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
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	white (opaque)	Score	
Shape		Size	
Flavor	CITRUS	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61578-302-01	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/01/2012	

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(61578-301, 61578-302, 61578-303)

Revised: 12/2022

Dental Alliance Holdings LLC