

EVEREST- stannous fluoride rinse
Alpine Dental, Inc.

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.

Active Ingredient

Stannous Fluoride, 0.63%

Purpose

Anticavity/Antigingivitis

Uses

- Aids in the prevention of dental decay
- Helps prevent gingivitis
- Helps interfere with harmful effects of plaque associated with gingivitis

Warnings

Keep out of reach of children under 6 years of age. If more than used for rinsing is swallowed, get medical help or contact a Poison Control Center right away.

Do not swallow.

Directions

- Do not use before mixing with water
- Adults and children 6 years of age and older:
 - Use once per day after brushing your teeth with toothpaste
 - Remove cap and replace with pump
 - Rotate spout counter clockwise to extend
 - Depress pump until rinse comes to the tip of the pump
 - Pump 1/8 fl. oz. into a cup.
 - Add water to the line (1 fl. oz.) on cup.
 - Mix using bristle end of toothbrush
 - Vigorously swish rinse between your teeth for 1 min. and then spit out.
 - Do not swallow the rinse
 - Do not eat or drink for 30 min. after rinsing
 - Instruct children under 12 in good rinsing habits to minimize swallowing.
 - Supervise children as necessary until capable of using without supervision
- Children under 6: Consult a dentist or doctor

Other Information

- Store at room temperature 59 – 86°F (15 – 30°C).
- This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

Inactive Ingredients

Edetic acid, Flavor, Glycerin, Saccharin Sodium, Xylitol

For a Healthier & Happier Mouth

EVEREST Periodontal Rinse works immediately to disinfect, prevent decay, and reduce painful tooth & gum sensitivity.

Gentle on your teeth and tough on cavities - for a deeper clean you'll feel all day.

Prevents Gingivitis

Reduce Gum Bleeding

Plaque Crusher

Freshens Breath

Manufactured by:

Alpine Dental, Inc.

Brooklyn, NY 11218

1-800-553-3682

Made in USA

Everest Oral Care

Perio Maintenance Oral Rinse

Antigingivitis + Anticavity

Advanced Fluoride Concentrate with Xylitol

Alcohol Free

Fruit

10 fl oz (296 mL)

<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Stannous fluoride, 0.63%</td> <td>Anticavity/Antigingivitis</td> </tr> </table> <p>Uses Aids in the prevention of dental decay • helps prevent gingivitis • helps interfere with harmful effects of plaque associated with gingivitis.</p> <p>Warnings Keep out of reach of children under 6 years of age. If more than used for rinsing is swallowed, get medical help or contact a Poison Control Center right away. Do not swallow.</p> <p>Directions</p> <ul style="list-style-type: none"> Do not use before mixing with water. Adults and children 6 year of age and older: <ul style="list-style-type: none"> Use once a day after brushing your teeth with a toothpaste Remove cap and replace with pump. Rotate spout counter clockwise to extend Depress pump until rinse comes to the tip of the pump Pump 1/8 fl. oz. into a cup. Add water to line (1 fl. oz.) on cup; Mix using bristle end of toothbrush Vigorously swish rinse between your teeth for 1 min. and then spit out. Do not swallow the rinse. Do not eat or drink for 30 min. after rinsing. Instruct children under 12 in good rinsing habits to minimize swallowing. Supervise children as necessary until capable of using without supervision. Children under 6: Consult a dentist or doctor. <p>Other Information</p> <ul style="list-style-type: none"> Store at room temperature 59-86°F (15-30°C) This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist. <p>Inactive Ingredients Edetic Acid, Flavor, Glycerin, Saccharin Sodium, Xylitol</p>	Active Ingredient	Purpose	Stannous fluoride, 0.63%	Anticavity/Antigingivitis	<p>For a Healthier & Happier Mouth</p> <p>EVEREST® Periodontal Rinse works immediately to disinfect, prevent decay, and reduce painful tooth & gum sensitivity.</p> <p>Gentle on your teeth and tough on cavities - for a deeper clean you'll feel all day.</p> <ul style="list-style-type: none"> Prevents Gingivitis Reduce Gum Bleeding Plaque Crusher Freshens Breath <p>Manufactured by: Alpine Dental Inc. Brooklyn, NY 11218 1800.653.3682 MADE IN USA</p>	 <p>PERIO MAINTENANCE</p> <p>Oral Rinse</p> <p>ANTINGIVITIS + ANTICAVITY Advanced Fluoride Concentrate With Xylitol</p> <p>ALCOHOL FREE FRUIT 10 FL. OZ. (296ml)</p>	<p>The Peak of Oral Care™</p>  <ul style="list-style-type: none"> ALCOHOL FREE DYE FREE PARABEN FREE GLUTEN FREE
Active Ingredient	Purpose						
Stannous fluoride, 0.63%	Anticavity/Antigingivitis						

EVEREST

stannous fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83199-101
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.63 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83199-101-10	269 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/19/2022	

Labeler - Alpine Dental, Inc. (037301378)

Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(83199-101)

Revised: 8/2022

Alpine Dental, Inc.