

ORAL DEFENSE FLUORIDE RINSE- sodium fluoride mouthwash

Oral Defense, 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.

Oral Defense Fluoride Rinse

Drug Facts

Active Ingredients

Sodium Fluoride .05% (0.22% w/v fluoride ion)

Purpose

Anti-cavity

Uses

Aids in the prevention of dental cavities

Warnings

Do not swallow. In case of accidental ingestion, seek medical help or contact a poison control center immediately. Cold weather may cloud this product. Properties are not affected.

Keep out of the reach of children.

Directions

Adults and children 6 years of age and older

- Use once a day, preferably before bedtime, after brushing and flossing thoroughly.
- For mature adults with gum recession, it is beneficial to use an interdental proxy brush (toothpick type plastic brush) to remove all food debris between all teeth.
- Use 10ml (1/3oz) and vigorously swish between the teeth for 1 minute. Spit out. Do not swallow.
- Supervise children over 6 years of age until capable of using without supervision.
- Consult with a dentist or doctor for use with children under 6 years of age.
- Do not take in food or drink for 30 minutes after application.

Inactive Ingredients

purified water, glycerin, propylene glycol, sorbitol, polysorbate 80, poloxamer 407, flavor, versene, cetylpyridinium chloride, sodium lauroyl sarcosinate, sodium saccharin, sodium hydroxide, citric acid, natamycin, FD and C green #5, FD and C red #33.

Labels

NEW Oral Defense™ Vanilla-Mint Flavor

Oral Defense™

Anti-Bacterial & Anti-Cavity Fluoride Rinse

Paraben & Alcohol Free

Strengthens Teeth and Provides Exceptional relief for symptoms of:

- Canker sores
- Dry mouth conditions
- Oral lesions from Chemo & Radiation Therapies
- Diabetes
- Gum irritations and Disease
- Lichen Plannus

Kills Bad Breath Bacteria on Contact

MADE IN THE U.S.A.
16 FL. OZ (474 ml)

ORAL DEFENSE

NOT JUST ANOTHER FLUORIDE MOUTH RINSE

Oral Defense LLC pioneered the use of cetylpyridinium chloride, a powerful bactericide, along with several key ingredients to provide an exceptionally efficient tool to fight oral diseases. Now Oral Defense is formulated with fluoride to provide ultimate protection against cavities.

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Questions or comments ? 1-800-355-9621 Manufactured Exclusively for Oral Defense LLC • Spokane, WA 99205	

Do not use if seal on bottle is not intact.
Patented Form # 7128998
www.neworaldefense.com



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sodium fluoride mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52644-002
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	.2418 g in 474 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM ANHYDROUS (UNII: I4807BK602)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
NATAMYCIN (UNII: 8O0C852CPO)	
MINT (UNII: FV98Z8G1TP)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	turquoise (Blue green)	Score	
Shape		Size	
Flavor	VANILLA (Vanilla Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52644-002-00	474 mL in 1 BOTTLE, PLASTIC		
2	NDC:52644-002-02	60 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/31/2010	

Labeler - Oral Defense, LLC (962643164)

Establishment

Name	Address	ID/FEI	Business Operations
Coastal Products Company		782445688	manufacture(52644-002)