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

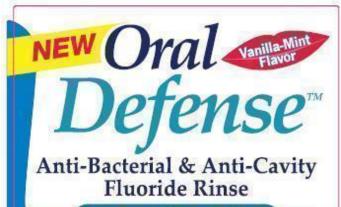
Adults and children 6 years of age and older

- 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 suing 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



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

Drug Facts

Active Ingredient

Liverida 0.05% (0.02% w/v fluoride ion)

Purpose

Aids in the prevention of dental cavities

Keep this out of the reach of children. 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.

Directions

- Directions

 Adults and children 6 years of age and older

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Questions or comments 7 1-800-355-9621 Manufactured Exclusively for Oral Defense LLC • Spokane, WA 99205

Do not use if seel on bottle is not intact, Patented Formula 7128898 www.neworaldefense.com





ORAL DEFENSE FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

HUMAN OTC DRUG NDC:52644-002 Product Type Item Code (Source)

ORAL Route of Administration

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYLPYRIDINIUM CHLO RIDE (UNII: D9 OM4SK49 P)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SO DIUM ANHYDRO US (UNII: 14807BK602)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
NATAMYCIN (UNII: 800C852CPO)	
MINT (UNII: FV98Z8GITP)	
SODIUM LAURO YL SARCO SINATE (UNII: 632GS99618)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

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)	

Revised: 4/2013 Oral Defense, LLC