

ORAL DEFENSE- sodium fluoride paste, dentifrice

Oral Defense

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.

Drug Facts

Purpose

Anti-Cavity toothpaste

Active Ingredient

Sodium Fluoride 0.25% (0.14 w/v Fluoride Ion)

Use

Aids in prevention of dental cavities and gingivitis.

Warnings

Children under two years of age: Consult a dentist or physician. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of the reach of children under 6 years of age.

Directions

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

For maximum benefits, brush for 1 minute at bedtime and use with Oral Defense Fluoride Rinse.

Question and Comments?

1-800-355-9621 • 1-509-326-6693 Office

Manufactured for: Oral Defense LLC, P.O. Box 8267 Spokane, WA 99203

Patent No. US 6,861,047B

Inactive Ingredients

Sorbitol, Purified Water, Glycerin, Hydrated Silica, Sodium Lauroyl Sarcosinate, Cellulose Gum, Flavor, Titanium Dioxide, Cetylpyridinium Chloride, Citric Acid, Sodium Saccharin, FD&C Blue No. 1, Dehydroacetic Acid.



Oral Defense

Recommended by dentists for those that experience:

- ▶ Bleeding Gums
- ▶ Gingivitis
- ▶ Canker Sores
- ▶ Sores from Dry Mouth conditions

The Gentle Toothpaste

In comparative testing to measure the irritation potential of the detergent formulation of 5 major brands of toothpastes, it was found that the Oral Defense formulation demonstrated a 40 fold decrease in damage to cellular membranes. This gentle formulation allows for a most comfortable experience when brushing.

The Tough Toothpaste

Oral Defense toothpaste contains fluoride and antibacterial ingredient compounds to not only enhance enamel resistance to cavities but control bacterial and fungal organisms associated with gingivitis and periodontitis

www.neworaldefense.com

Recommended by Dentists, Orthodontists and Hygienists

Oral Defense represents Revolutionary Pioneered Technology and Scientific Breakthroughs in dental health care. Visit your dentist regularly.

Oral Defense
FEEL THE SHIELD™
Protection you can trust
JMJ



Recommended by Dentists and Hygienists to help maintain mouth tissues by fighting gingivitis and inflammation of oral tissues.

Neutral pH • Promotes a Healthier Mouth

Helps to Prevent Cavities and Reduce Tarter Formation

Oral Defense



FEEL THE SHIELD™

NET WT 4 OZ (113.5 G)

Formulated for oral conditions associated with:

- Diabetes • Arthritis
- Chemo-radiation therapies
- Drug therapies • Orthodontics

Tough on Germs • Gentle on Tissue

Oral Defense

Cool Mint

Sodium Lauryl Sulfate FREE

FEEL THE SHIELD™

JMJ

NET WT 4 OZ (113.5 G)

Drug Facts

Active Ingredient: Sodium Fluoride 0.25% (0.14 w/v Fluoride Ion)

Purpose: Anticavity toothpaste

Use: Aids in prevention of dental cavities, and gingivitis.

Warnings: ■ Children under two years of age: Consult a dentist or physician. ■ If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of the reach of children under 6 years of age.

Question & Comments? 1-800-355-9621 • 1-509-326-6693 Office

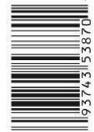
Manufactured for Oral Defense LLC, P.O. Box 6267 Spokane, WA 99203 Patent No. US 6,861,047 B1

Drug Facts (continued)

Directions: ■ Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. ■ Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). ■ Supervise children as necessary until capable of using without supervision.

For maximum benefits, brush for 1 minute at bedtime and use with Oral Defense Fluoride Rinse.

Inactive Ingredients: Sorbitol, Purified Water, Glycerin, Hydrated Silica, Sodium Lauryl Sarcosinate, Cellulose Gum, Flavor, Titanium Dioxide, Cetylpyridinium Chloride, Citric Acid, Sodium Saccharin, FD&C Blue No. 1, Dehydroacetic Acid



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50927
Oral Defense
FEEL THE SHIELD™
Protection you can trust
JMJ
A247

NEW Oral **Defense**® *Antibacterial-Tough on Germs Promotes Healthier Gums*

Formulated by Dentists
Helps prevent cavities and inflammation of mouth tissues

Cool Mint

Anticavity Fluoride Toothpaste NET WT. 4 OZ (118g)

Ideal for the following oral applications:

- Dry Mouth
- Arthritis
- Diabetes
- Chemo-radiation Therapies
- Gingivitis–Bleeding gums
- Helps to prevent cavities
- Helps fight oral infections

SEALED FOR YOUR PROTECTION. REMOVE SEAL FROM UNDER CAP. DO NOT USE IF SEAL IS NOT PRESENT.

DIRECTIONS: Adults and children two years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day or as directed by a dentist or physician. Because of the high foaming action of this toothpaste, place 1/2 the amount that you normally use with any other toothpaste on the brush.

- For maximum benefits, brush for 1 minute at bedtime.
- Instruct children under six years of age in good brushing and rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under two years of age: Consult a dentist or physician.

WARNING: Keep out of reach of children under six years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center right away.

For cleaner teeth, healthy gums and fresh breath, brush after meals and use Oral Defense Rinse. Visit your dentist regularly

Active Ingredient: Sodium Fluoride 0.25% (0.14 w/v Fluoride Ion).

Manufactured for: **Oral Defense LLC**
Spokane, WA 99203

Questions or Comments?
Call 1-800-355-9621

Patent No. US 6,681,047 B1
JMJ

ORAL DEFENSE

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52644-003
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	.14 g in 118 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SORBITOL (UNII: 506T60A25R)	
water (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

CETYLPYRIDINIUM (UNII: CUB7J10JV3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	

Product Characteristics

Color	blue (blue (FD and C Blue No. 1))	Score	
Shape		Size	
Flavor	MINT (MINT (Fluoride Toothpaste Flavor Mint))	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52644-003-01	1 in 1 BOX		
1	NDC:52644-003-00	118 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/12/2011	

Labeler - Oral Defense (962643164)

Establishment

Name	Address	ID/FEI	Business Operations
Coastal Products Company		782445688	manufacture(52644-003)

Revised: 1/2013

Oral Defense