

## **ORAL DEFENSE- cetylpyridinium chloride 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 Mouth Rinse**

#### **Drug Facts**

##### **Active Ingredients**

Cetylpyridinium Chloride 0.1%

##### **Purpose**

Antigingivitis/Anti-Plaque

##### **Uses**

- Canker sores
- Dry mouth conditions
- Oral lesions from chemo and radiation therapies
- Diabetes
- Gum irritations and disease
- Lichen Plannus

##### **Warnings**

See a dentist if symptoms or conditions persist after regular use.

##### **Keep 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**

###### **Healthy Mouth**

Rinse with 1 capful after brushing your teeth with Oral Defense toothpaste when needed for breath refreshment and to maintain healthy mouth tissue.

###### **Red, Bleeding gums and inflamed mouth**

For best and speedy results use with Oral Defense toothpaste. Use 1 capful after brushing with Oral Defense Toothpaste for 1 minute. If the lesions or sores re in one area, hold the capful of rinse in your mouth over the lesion for 1 minute, or if not possible to hold for 1 minute then use twice, 1 capful for 30 seconds each before spitting out. The most critical time of application is at bedtime, when no food or water is to be consumed after use, as the rinse has ingredients that have a long effective residual

throughout the night when healing is best to occur.

## Inactive Ingredients

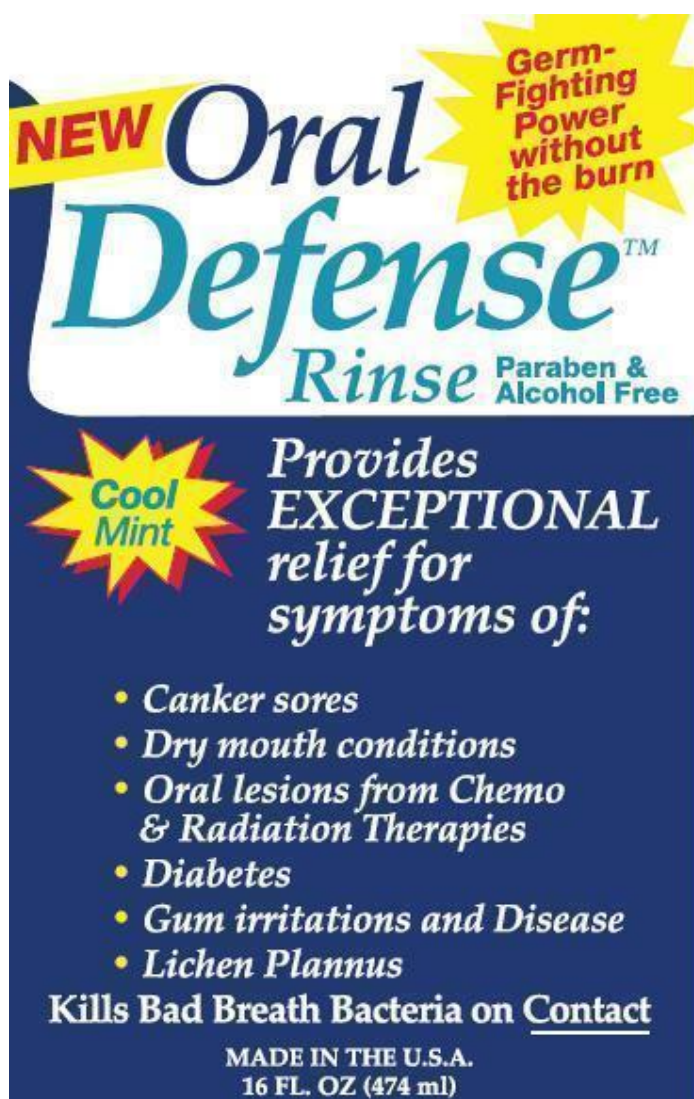
purified water, glycerin, propylene glycol, sorbitol, polysorbate 80, poloxamer 407, mentha piperita (peppermint oil), versene, sodium lauroyl sarcosinate, sodium hydroxide, citric acid, menthol, natamycin, FD and C green #5

## Questions or comments

1-800-355-9621

Manufactured Exclusively for Oral Defense, LLC Spokane, WA 99205

## Labeling



**NEW** Oral **Defense**<sup>TM</sup> Rinse **Paraben & Alcohol Free**

**Germ-Fighting Power without the burn**

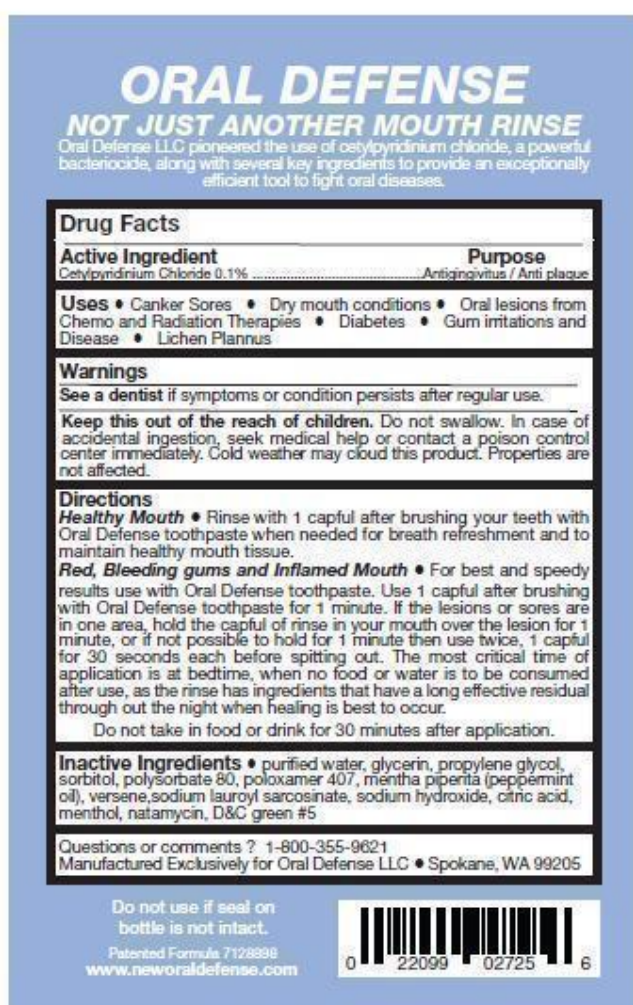
**Cool Mint**

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 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.

Drug Facts	
Active Ingredient	Purpose
Cetylpyridinium Chloride 0.1%	Antigingivitis / Anti plaque

**Uses** • Canker Sores • Dry mouth conditions • Oral lesions from Chemo and Radiation Therapies • Diabetes • Gum irritations and Disease • Lichen Plannus


**Warnings**  
See a dentist if symptoms or condition persists after regular use.  
**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**  
**Healthy Mouth** • Rinse with 1 capful after brushing your teeth with Oral Defense toothpaste when needed for breath refreshment and to maintain healthy mouth tissue.  
**Red, Bleeding gums and Inflamed Mouth** • For best and speedy results use with Oral Defense toothpaste. Use 1 capful after brushing with Oral Defense toothpaste for 1 minute. If the lesions or sores are in one area, hold the capful of rinse in your mouth over the lesion for 1 minute, or if not possible to hold for 1 minute then use twice, 1 capful for 30 seconds each before spitting out. The most critical time of application is at bedtime, when no food or water is to be consumed after use, as the rinse has ingredients that have a long effective residual through out the night when healing is best to occur.  
Do not take in food or drink for 30 minutes after application.

**Inactive Ingredients** • purified water, glycerin, propylene glycol, sorbitol, polysorbate 80, poloxamer 407, mentha piperita (peppermint oil), versene, sodium lauroyl sarcosinate, sodium hydroxide, citric acid, menthol, natamycin, D&C green #5

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 Formula 7128998  
www.neworaldefense.com



0 22099 02725 6

**NEW** **Oral Defense<sup>TM</sup> Rinse** **Paraben & Alcohol Free**

**Germ-Fighting Power without the burn**

**Cool Mint**

**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 USA 2 fl oz. (60ml)

## ORAL DEFENSE

NOT JUST ANOTHER 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.

Drug Facts	
Active Ingredient	Purpose
Cetylpyridinium Chloride 0.1% ....	Antigingivitis/Anti plaque
Uses	
Canker Sores • Dry mouth conditions • Oral lesions from Chemo and Radiation Therapies • Diabetes • Gum irritations and Disease • Lichen Plannus	
Warnings	
See a dentist if symptoms or condition persists after regular use.	
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	
<b>Healthy Mouth</b> • Rinse with 1 capful after brushing your teeth with Oral Defense toothpaste when needed for breath refreshment and to maintain healthy mouth tissue. <b>Red, Bleeding gums and Inflamed Mouth</b> • For best and speedy results use with Oral Defense toothpaste. Use 1 capful after brushing with Oral Defense toothpaste for 1 minute. If the lesions or sores are in one area, hold the capful of rinse in your mouth over the lesion for 1 minute, or if not possible to hold for 1 minute then use twice, 1 capful for 30 seconds each before spitting out. The most critical time of application is at bedtime, when no food or water is to be consumed after use, as the rinse has ingredients that have a long effective residual through out the night when healing is best to occur. Do not take in food or drink for 30 minutes after application.	
Inactive Ingredients	
purified water, glycerin, propylene glycol, sorbitol, polysorbate 80, poloxamer 407, mentha piperita (peppermint oil), versene, sodium lauroyl sarcosinate, sodium hydroxide, citric acid, menthol, natamycin, D&C green #5	
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 Formula 7128898  
[www.neworaldefense.com](http://www.neworaldefense.com)

## ORAL DEFENSE

cetylpyridinium chloride mouthwash

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52644-001
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII:CUB7JJ0JV3)	CETYL PYRIDINIUM CHLORIDE	.47 mL in 474 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
NATAMYCIN (UNII: 8O0C852CPO)	
SODIUM LAUROYL SARCO SINATE (UNII: 632GS99618)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

### Product Characteristics

<b>Color</b>	turquoise (Blue/Green)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Cool mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52644-001-00	474 mL in 1 BOTTLE, PLASTIC		
2	NDC:52644-001-02	60 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/26/2010	

**Labeler** - Oral Defense, LLC (962643164)

### Establishment

Name	Address	ID/FEI	Business Operations
Coastal Products Company		782445688	manufacture(52644-001)

Revised: 5/2012

Oral Defense, LLC