# GOOD HYGIENE THERAPEUTIC MOUTH RINSE- hydrogen peroxide debriding agent liquid

### **Good Hygiene Company**

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.

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### **Good Hygiene Therapeutic Mouth Rinse**

### **Drug Facts**

### **Active Ingredient**

Hydrogen Peroxide 1.5% (w/v)

### **Purposes**

Oral debriding agent/oral wound cleanser

#### Uses

• for temporary use to cleanse canker sores and minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums

### Warnings

**Do not use** this product for more than 7 days unless directed by a dentist or physician.

When using this product, do not swallow.

# Stop use and ask a doctor if

- sore mouth symptoms do not improve within 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

**Keep out of reach of children**. If more than used for rinsing is accidentally swallowed,

get medical help or contact a Poison Control Center right away.

#### **Directions**

- Adults and children 2 years of age and older: rinse half capful (two teaspoons or 10 mL) around in the mouth over affected area for at least 1 minute, then spit out
- Use up to 4 times daily after meals and at bedtime or as directed by a dentist or physician
- Children under 12 years of age should be supervised in the use of the product
- Children under 2 years of age: consult a dentist or physician

**Other Information**Store at controlled room temperature 68 – 77°F (20 – 25°C) Do not use if the safety seal is broken or missing.

*Inactive Ingredients:* Deionized water, xylitol, glycerin, natural flavor, poloxamer 407, zinc citrate, cardamom, sodium benzoate

# **Product Labeling**

### **GOOD**

# hygiene

# THERAPEUTIC MOUTH RINSE

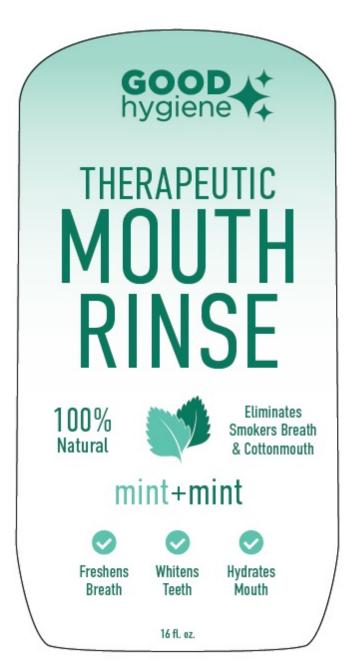
mint + mint

Freshens Whitens Hydrates Breath Teeth Mouth

16 fl. oz.

Good Hygiene Co. Los Angeles, CA 91352 practice@goodhygiene.com Made with ♥ in the USA.

Mint + Mint



# #PracticeGoodHygiene

No Alcohol • Gluten Free • Cruelty Free • Non-GMO Fluoride Free • Paraben Free • Sulfate (SLS) Free • Vegan

Formulated for optimum oral health. Light foaming action works thoroughly to flush away food particles from gums, braces, and dentures to freshen breath, whiten teeth, and achieve a whole mouth clean. Cleans and promotes healing of canker sores, cheek bites, mouth burns, oral and gum irritations. Kills bad breath germs.

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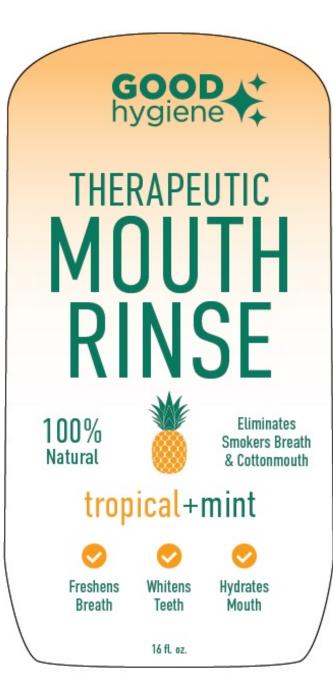
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PLEASE TRECYCLE Questions or Comments? Good Hygiene Co. Los Angeles, CA 91352 practice@goodhygiene.com Made with ♥ in the USA.



**Tropical + Mint** 



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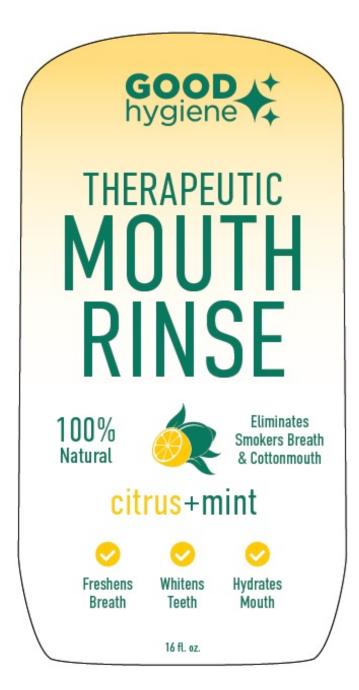


PLEASE PRECYCLE

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Citrus + Mint



# #PracticeGoodHygiene

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#### GOOD HYGIENE THERAPEUTIC MOUTH RINSE

hydrogen peroxide debriding agent liquid

### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:81439-100

**Route of Administration** ORAL

#### Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength	
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE -	HYDROGEN	1.5 g	

UNII:BBX060AN9V)	PEROXIDE	in 100 mL
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Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
XYLITOL (UNII: VCQ006KQ1E)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
ZINC CITRATE (UNII: K72I3DEX9B)				
CARDAMOM (UNII: 8BC4CUT4JL)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:81439- 100-16	475 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/01/2021	05/12/2023

# GOOD HYGIENE THERAPEUTIC MOUTH RINSE

hydrogen peroxide debriding agent liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81439-110
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	1.5 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	

POLOXAMER 407 (UNII: TUF2IVW3M2)	
ZINC CITRATE (UNII: K72I3DEX9B)	
CARDAMOM (UNII: 8BC4CUT4JL)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	<b>1</b> NDC:81439- 110-16	475 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/01/2021	
OTC monograph not			Dat

# **GOOD HYGIENE THERAPEUTIC MOUTH RINSE**

hydrogen peroxide debriding agent liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81439-120	

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
	HYDROGEN PEROXIDE	1.5 g in 100 mL		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
XYLITOL (UNII: VCQ006KQ1E)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
ZINC CITRATE (UNII: K72I3DEX9B)				
CARDAMOM (UNII: 8BC4CUT4JL)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

Packaging		

#	item code	Package Description	Date	Date		
1	NDC:81439- 120-16	475 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2021			
Marketing Information						
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
O1 fin	FC monograph ne al	part356	05/01/2021			

Marketing Start Marketing End

# Labeler - Good Hygiene Company (131413215)

# **Registrant -** Good Hygiene Company (131413215)

Revised: 5/2023 Good Hygiene Company