

**ANTISEPTIC ORAL CLEANSER- hydrogern peroxide mouthwash
OLD EAST MAIN CO.**

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.

**Alcohol-Free Mint Peroxide Rinse
462.002/462.AA rev 1**

Active ingredient

Hydrogen Peroxide 1.5%w/v

Purpose

Oral debriding agent/Oral wound cleanser

Use

- aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth
- for temporary use in cleansing minor wounds or minor gum inflammation resulting from minor dental procedures, dentures, orthodontic appliances, accidental injury, or other irritations of the mouth and gums
- for temporary use to cleanse canker sores
- assists in the removal of foreign material from minor oral wounds

Warnings

Do not use this product

this product for more than 7 days unless directed by a dentist or doctor. If sore mouth symptoms do not improve in 7 days; if irritation, pain, or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or doctor promptly

When using this product,

do not swallow

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 two teaspoons (10 mL) around the mouth 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 should be supervised in the use of the product
- children under 2 years of age: consult a dentist or doctor

Other information

store at controlled room temperature 68-77°F (20-25°C)

Inactive ingredients

water, sorbitol, propylene glycol, poloxamer 338, polysorbate 20, flavor, sodium saccharin, blue 1

100% SATISFACTION GUARANTEED (888)- 309-9030

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100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

principal display panel

Since 1903

Rexall

Alcohol-Free

Peroxide Rinse

Oral debriding agent

Hydrogeben Peroxide

- Cleans and helps relieve minor mouth and gun irritation

smoothing Mint

8 FL OZ (236 mL)



ANTISEPTIC ORAL CLEANSER

hydrogen peroxide mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-171
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	150 mg in 100 L

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

SORBITOL (UNII: 506T60A25R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-171-34	.236 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/19/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/19/2009	

Labeler - OLD EAST MAIN CO. (068331990)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55910-171)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55910-171)

Revised: 9/2022

OLD EAST MAIN CO.