

## **ORAL SORE ANTISEPTIC- hydrogen peroxide, menthol liquid**

### **Walgreens**

*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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### **undefined**

### **active ingredients**

Hydrogen peroxide 1.5% (w/v)

Menthol 0.1% (w/v)

### **purpose**

Oral debriding agent/Oral antiseptic

Oral pain reliever

### **uses**

- first aid to help protect against bacterial contamination in minor oral wounds
- for temporary pain relief and ■ temporary use in cleansing minor wounds or minor gum inflammation resulting from:
  - minor dental procedures
  - dentures
  - orthodontic appliances
  - accidental injury
  - other irritations of the mouth and gums
  - canker sores
- aids in the removal of:
  - phlegm
  - mucus
  - other secretions associated with occasional sore mouth
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  - phlegm
  - mucus
  - other secretions associated with occasional sore mouth

### **warnings**

Stop use and ask a doctor if

- sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops
- sore mouth symptoms do not improve in 7 days

### **When using this product**

- do not swallow

- do not use more than 7 days unless directed by a dentist or doctor
- do not exceed recommended dosage

### **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 - swish two teaspoons (10 mL) around the mouth for at least 1 minute, then spit out; use up to 4 times daily 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 doctor

### **other information**

- store at controlled room temperature 68-77°F (20-25°C)
- keep away from heat or direct sunlight

### **inactive ingredients**

alcohol (4.1% v/v), blue 1, disodium EDTA, methyl salicylate, phosphoric acid, poloxamer 338, polysorbate 20, sodium saccharin, sorbitol, water

### **SAFETY SEAL**

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

### **questions**

Call 1-800-925-4733

### **ADVERSE REACTIONS SECTION**

DISTRIBUTED BY: WALGREEN CO., 200 WILMOT RD., DEERFIELD, IL 60015

100% SATISFACTION GUARANTEED [walgreens.com](http://walgreens.com)

MADE IN U.S.A. WITH U.S. AND FOREIGN COMPONENTS

Our pharmacist recommend the Walgreens brand. We invite you to compare to national brands.

This product is not manufactured or distributed by

Church & Dwight Co., Inc owner of the trademark Orajel

## **Principal display panel**

Walgreens

WALGREENS - PHARMACIST RECOMMENDED

Compare to the active ingredients in Orael Antiseptic Rinse

Antiseptic

Rinse

ORAL PAIN RELIEVER & DEBRIDING AGENT WITH HYDROGEN PEROXIDE & MENTHOL

Cleans Mouth Sores

- For mouth sores, including gum irritation from braces or dentures & canker sores
- Temporary pain relief for mouth sores
- Kills germs & bacterial

Mint flavor

16 FL OZ (473 mL)

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Walgreens



Compare to the active ingredients  
in Orajel™ Antiseptic Rinse™

# Antiseptic Rinse

ORAL PAIN RELIEVER & DEBRIDING AGENT  
WITH HYDROGEN PEROXIDE & MENTHOL

## Cleans Mouth Sores

- For mouth sores, including gum irritation from braces or dentures & canker sores
- Temporary pain relief for mouth sores
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16 FL OZ (473 mL)

Mint  
flavor

L0018058FC

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## ORAL SORE ANTISEPTIC

hydrogen peroxide, menthol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1045
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	1.5 mg in 1 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
water (UNII: 059QF0KOOR)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1045-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/15/2020	

**Labeler** - Walgreens (008965063)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(0363-1045)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(0363-1045)

