

**ORAL SORE ANTISEPTIC- hydrogen peroxide, menthol liquid**  
**RETAIL BUSINESS SERVICES , 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.*

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**Oral Sore Antiseptic Rinse**  
**024.000/024AA-AB**

**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

**Warnings**

for this product

**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

DISTRIBUTED BY ADUSA DISTRIBUTION, LLC

SALISBURY, NC 28147

For product questions or concerns,

contact us at 1-833-992-3872

Quality guaranteed or your money back.

\*This product is not manufactured or distributed by Church & Dwight Co., Inc. distributor of Orajel Antiseptic Rinse Mouth Sores.

DSP-TN-21091 DSP-MO-20087

## **Principal display panel**

CAREONE

Compare to Orajel Antiseptic Rinse Mouth Sores\*

ORAL SORE

ANTISEPTIC RINSE

ORAL PAIN RELIEVER

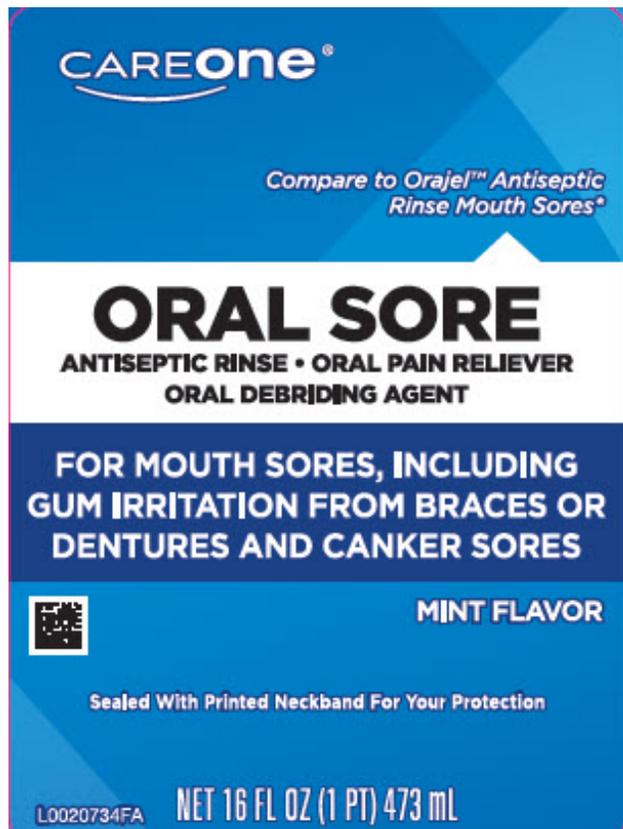
ORAL DEBRIDING AGENT

FOR MOUTH SORES, INCLUDING GUM IRRITATIONS FROM BRACES OR DENTURES AND  
CANKER SORES

MINT FLAVOR

Sealed With Printed Neckband For Your Protection

NET 16 FL OZ (1 PT) 473 mL



## ORAL SORE ANTISEPTIC

hydrogen peroxide, menthol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-024
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	15 mg in 1 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 mL

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-024-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/13/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/13/2023	

**Labeler** - RETAIL BUSINESS SERVICES , LLC (967989935)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-024)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-024)

Revised: 4/2023

RETAIL BUSINESS SERVICES , LLC