

## **SORE MOUTH CLEANSER- hydrogen peroxide mouthwash**

### **Rite Aid**

*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.*

-----

### **Drug Facts Rite 462.002/462AA rev 1**

#### **active ingredient**

Hydrogen peroxide 150 mg/10mL

#### **Purpose**

Oral debriding agent/Oral wound cleanser

#### **Uses**

- aids in the removal of phlgem, 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, acidental 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**

For this product

#### **Do not use**

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 redenss 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

**Disclaimer**

This product is not manufactured or distributed by Colgate Oral Pharmaceuticals, distributor of Colgate Peroxyl Mouth Sore Rinse Alcohol-Free Mild Mint

**Adverse Reactions**

SATISFACTION GUARANTEE:

If you're not satisfied we'll happily refund your money.

DISTRIBUTED BY:

RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

[www.riteaid.com](http://www.riteaid.com)

**principal display panel**

Sealed with printed neckband for your protection

Compare to Colgate Peroxyl Mouth Sore Rinse Alcohol-Free Mild Mint

FREE FROM ALCOHOL FREE

PEROXIDE MOUTH RINSE

HYDROGEN PEROXIDE ORAL DEBRIDING AGENT

MINT

1.5% hydrogen peroxide cleans and helps relieve minor irritations

8 FL OZ (236 mL)



## SORE MOUTH CLEANSER

hydrogen peroxide mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-1462
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	1588 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLOXAMER 338</b> (UNII: F75JV2T505)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1462-3	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/03/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/03/2012	

**Labeler** - Rite Aid (014578892)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11822-1462)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11822-1462)

Revised: 4/2022

Rite Aid