

**ORAJEL ALCOHOL FREE ANTISEPTIC RINSE FOR ALL MOUTH SORES- hydrogen peroxide 1.5%, menthol 0.1% liquid**  
**Church & Dwight Canada Corp**

*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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**DRUG FACTS Orajel Alcohol Free Antiseptic Rinse**

***Active ingredient***

Hydrogen peroxide 1.5%

Menthol 0.1%

***Purpose***

Oral debriding agent/Oral antiseptic

Oral pain reliever

***Uses***

- first aid to help reduce bacteria in minor oral wounds
- for temporary pain relief and
- use in cleansing minor wounds or minor gum inflammation resulting from:
- minor dental procedures
- accidental injury
- orthodontic appliances
- canker sores
- dentures
- other irritations of the mouth and gums

Aids in the removal of

- phlegm
- mucus
- other secretions associated with occasional sore mouth

***Warnings***

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

**When using this product**

- do not swallow
- do not exceed recommended dosage

**Stop Use and see your physician promptly if**

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

**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***

- remove imprinted safety seal from bottle cap
- to remove child-resistant cap, squeeze smooth sides of cap while turning. Reclose tightly. Ready to use, no mixing needed.

Adults and children 2 years of age and older	Swish one-half capful (2 teaspoons=10mL) around the mouth over the affected area for at least 1 minute and then spit out. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or healthcare provider
Children under 12 years of age	Should be supervised in the use of this product
Children under 2 years of age	Consult a dentist or healthcare provider

**Other Information**

- cap tightly
- keep away from heat or direct sunlight
- do not use if safety seal is broken or missing

**Inactive ingredients** blue 1, disodium EDTA, methyl salicylate, phosphoric acid, poloxamer 338, polysorbate 20, propylene glycol, sodium saccharin, sorbitol, water

***Orajel Alcohol Free Antiseptic Rinse***

#1

*PAIN RELIEVER*

*BRAND FOR ADULTS*

*NEW*

***Orajel***

***ALCOHOL FREE Antiseptic rinse***

***FOR ALL MOUTH SORES***

***Canker Sores Cheek Bites Gum Irritation***

***Irritation from Dentures or Braces***

*Promotes Healing*

*Kills Bacteria*

*Provides Pain Relief*

*FRESH MINT*

*ORAL DEBRIDING AGENT / ANTISEPTIC RINSE / PAIN RELIEVER*

*16 FL OZ (473.2 mL)*

*Front Label OJLBF-00003-01.jpg*

4.8750"

**#1**  
PAIN RELIEVER  
BRAND FOR ADULTS

**NEW**

**Orajel™**  
**ALCOHOL FREE**

**Antiseptic Rinse**

**FOR ALL MOUTH SORES**

*Canker Sores • Cheek Bites • Gum Irritation  
Irritation from Dentures or Braces*

- ✓ **Promotes Healing**
- ✓ **Kills Bacteria**
- ✓ **Provides Pain Relief**

OJLBB-00003-01 70504012



**FRESH  
MINT**

ORAL ANESTHETIC AGENT/  
ANTISEPTIC RINSE/PAIN RELIEVER **16 FL OZ (473.2 mL)**

Back Label OJLBB-00003-01.jpg

3.3750



4.8750

# Drug Facts

## Active ingredients Purpose

Hydrogen peroxide 1.5% .....Oral debriding agent/  
Oral antiseptic

Menthol 0.1% .....Oral pain reliever

**Uses** ■ first aid to help reduce bacteria in minor oral wounds ■ for temporary pain relief and ■ use in cleansing minor wounds or minor gum inflammation resulting from:  
■ minor dental procedures ■ accidental injury  
■ orthodontic appliances ■ canker sores  
■ dentures ■ other irritations of the mouth and gums

Aids in the removal of: ■ phlegm ■ mucus ■ other secretions associated with occasional sore mouth

## Warnings

Do not use this product for more than 7 days unless directed by a dentist or healthcare provider

When using this product do not swallow ■ do not exceed recommended dosage

Stop use and see your physician promptly if ■ swelling, rash or fever develops ■ irritation, pain or redness persists or worsens ■ sore mouth symptoms do not improve in 7 days

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** ■ remove imprinted safety seal from bottle cap ■ to remove child-resistant cap, squeeze smooth sides of cap while turning. Reclose tightly. Ready to use, no mixing needed.

Adults and children  
2 years of age and older

Swish one-half capful (2 teaspoons = 10mL) around the mouth over the affected area for at least 1 minute and then spit out. Use up to 4 times daily after meals and at bedtime or as directed by a dentist or healthcare provider

Children under 12 years of age

Should be supervised in the use of this product

Children under 2 years of age

Consult a dentist or healthcare provider

**Other information** ■ cap tightly ■ keep away from heat or direct sunlight ■ do not use if safety seal is broken or missing

**Inactive ingredients** blue 1, disodium EDTA, methyl salicylate, phosphoric acid, poloxamer 338, polysorbate 20, propylene glycol, sodium saccharin, sorbitol, water

**Questions or comments?** call us at 1-800-952-5080 M-F 9am-5pm ET or visit our website at [www.oraljel.com](http://www.oraljel.com)

**SAFETY SEALED**

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Ewing, NJ 08620  
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## **ORAJEL ALCOHOL FREE ANTISEPTIC RINSE FOR ALL MOUTH SORES**

hydrogen peroxide 1.5%, menthol 0.1% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62864-759
<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	1.5 mL in 1 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<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>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62864-759-16	473.2 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/01/2014	

**Labeler** - Church & Dwight Canada Corp (253933600)

**Registrant** - Church & Dwight Co., Inc. (001211952)

### Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Canada Corp.		253933600	manufacture(62864-759)