# ORAJEL 2X GUM PAIN ALCOHOL-FREE- menthol and hydrogen peroxide rinse Church & Dwight Co., Inc.

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Orajel ™2x Gum Pain Rinse Alcohol-Free

**Drug Facts** 

Active ingredients	Purpose
Hydrogen peroxide 1.5%	Oral debriding agent/Oral
Trydrogen peroxide 1.5 %	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	Should be supervised in the
years of age	use of this product
Children under 2	Consult a dentist or healthcare
years of age	provider

### Other information

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

### **Inactive ingredients**

disodium EDTA, FD&C blue no.1, 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 <u>www.orajel.com</u>

### PRINCIPAL DISPLAY PANEL - 473.2 mL Bottle Label

1# ORAL PAIN RELIEF BRAND FOR ADULTS

Orajel ™ 2X GUM PAIN RINSE MEDICATED ALCOHOL FREE

### **EFFECTIVE ORAL PAIN RELIEF**

- Soothes & Cools Gums
- Kills Harmful Bacteria
- Promotes Healing

• Relieves Gum Irritation Caused by Dentures or Braces

ORAL DEBRIDING AGENT/ ANTISEPTIC RINSE/PAIN RELIEVER

Soothing MINT

16 FL OZ (473.2 mL)

OJLBF-01904-01 72025286

ORAL PAIN RELIEF BRAND

# **GUM PAIN RINSE**

# **ALCOHOL FREE**

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■ accidental injury orthodontic appliances canker sores other irritations of the mouth and gums ■ dentures Aids in the removal of: ■ phlegm ■ mucus ■ other secretions associated with occasional sore mouth Warnings

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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
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Directions 
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■ to remove child-resistant cap. squeeze smooth sides of cap while turning. Reclose tightly. Ready to use, no mixing needed.

Swish one-half capful (2 teaspoons = 10mL) around the mouth Adults and children 2 years of age and older 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

Consult a dentist or healthcare provider Children under 2 years of age

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

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### SAFETY SEALED

Church & Dwight Co., Inc. Ewing, NJ 08628 TM 2021 Church & Dwight Co., Inc. QJLBB-01904-01 72025285 Made in Canada



## ORAJEL 2X GUM PAIN ALCOHOL-FREE

menthol and hydrogen peroxide rinse

### **Product Information**

**HUMAN OTC DRUG** Item Code (Source) NDC:10237-799 **Product Type** 

**Route of Administration ORAL** 

### **Active Ingredient/Active Moiety**

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

Inactive Ingredients		
Ingredient Name	Strength	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
METHYL SALICYLATE (UNII: LAV5U5022Y)		
PHOSPHORIC ACID (UNII: E4GA8884NN)		
<b>POLOXAMER 338</b> (UNII: F75JV2T505)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		473.2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/15/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	01/15/2023	

# Labeler - Church & Dwight Co., Inc. (001211952)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Church & Dwight Canada Corp.		253933600	manufacture(10237-799)	

Revised: 11/2024 Church & Dwight Co., Inc.