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

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.

Orajel™ 2x Gum Pain Rinse
Alcohol-Free

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

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 **www.orajel.com**

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

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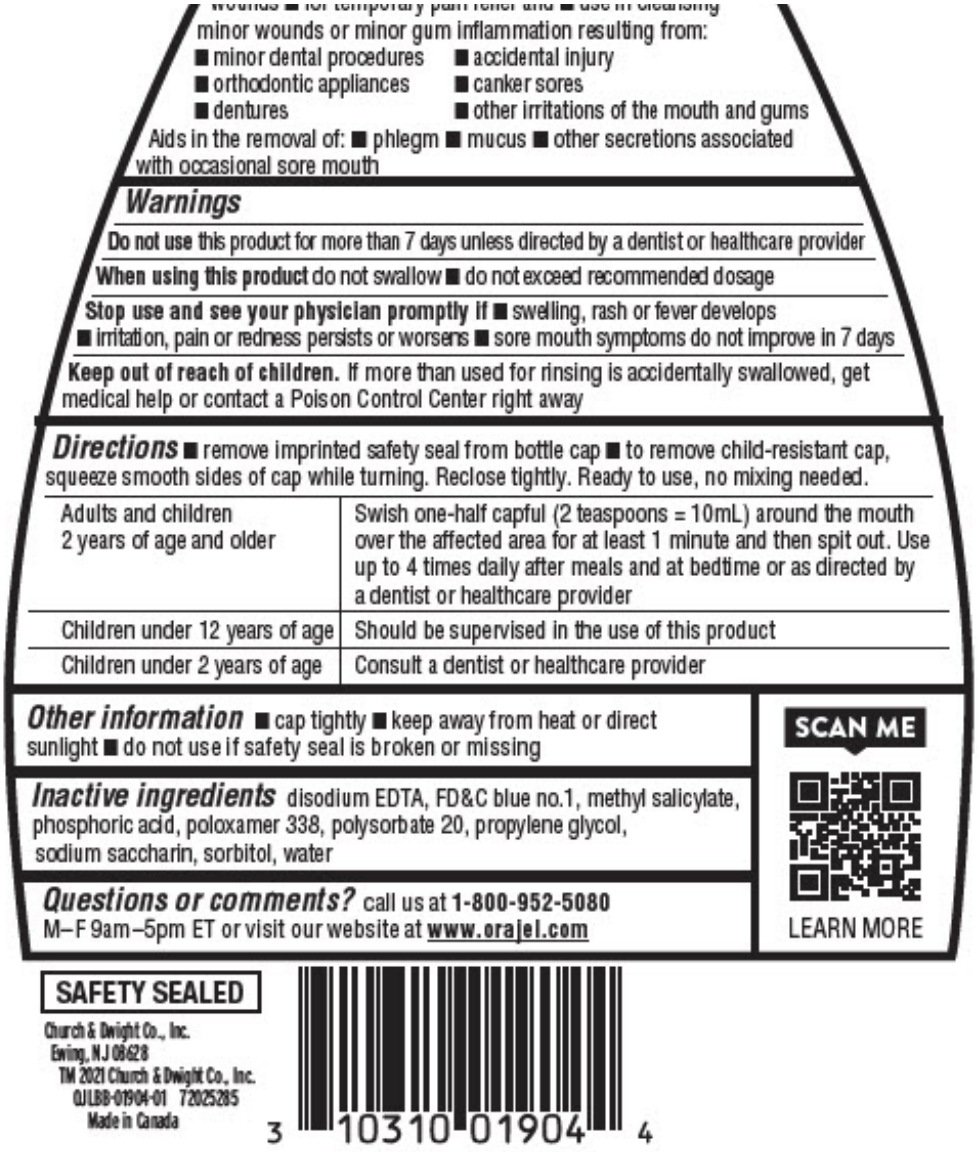

ORAJEL 2X GUM PAIN ALCOHOL-FREE

menthol and hydrogen peroxide rinse

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-799
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**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)	
Poloxamer 338 (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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-799-16	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 not final	part356	01/15/2023	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Canada Corp.		253933600	MANUFACTURE(10237-799)

Revised: 1/2023 Church & Dwight Co., Inc.