ORAJEL 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.

DRUG FACTS Orajel Antiseptic Rinse for All Mouth Sores

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 tesapoons=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 alcohol (4.1% by volume), blue 1, disodium EDTA, methyl salicylate, phosphoric acid, poloxamer 338, polysorbate 20, 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

Orajel Alcohol Free Antiseptic Rinse

#1

PAIN RELIEVER

BRAND FOR ADULTS

NOW WITH PAIN RELIEF!

Orajel

Antiseptic Rinse

FOR ALL MOUTH SORES

Canker Sores Cheek Bites Gum Irritation

Irritatrion from Dentures or Braces

Promotes Healing

Kills Bacteria

Provides Pain Relief

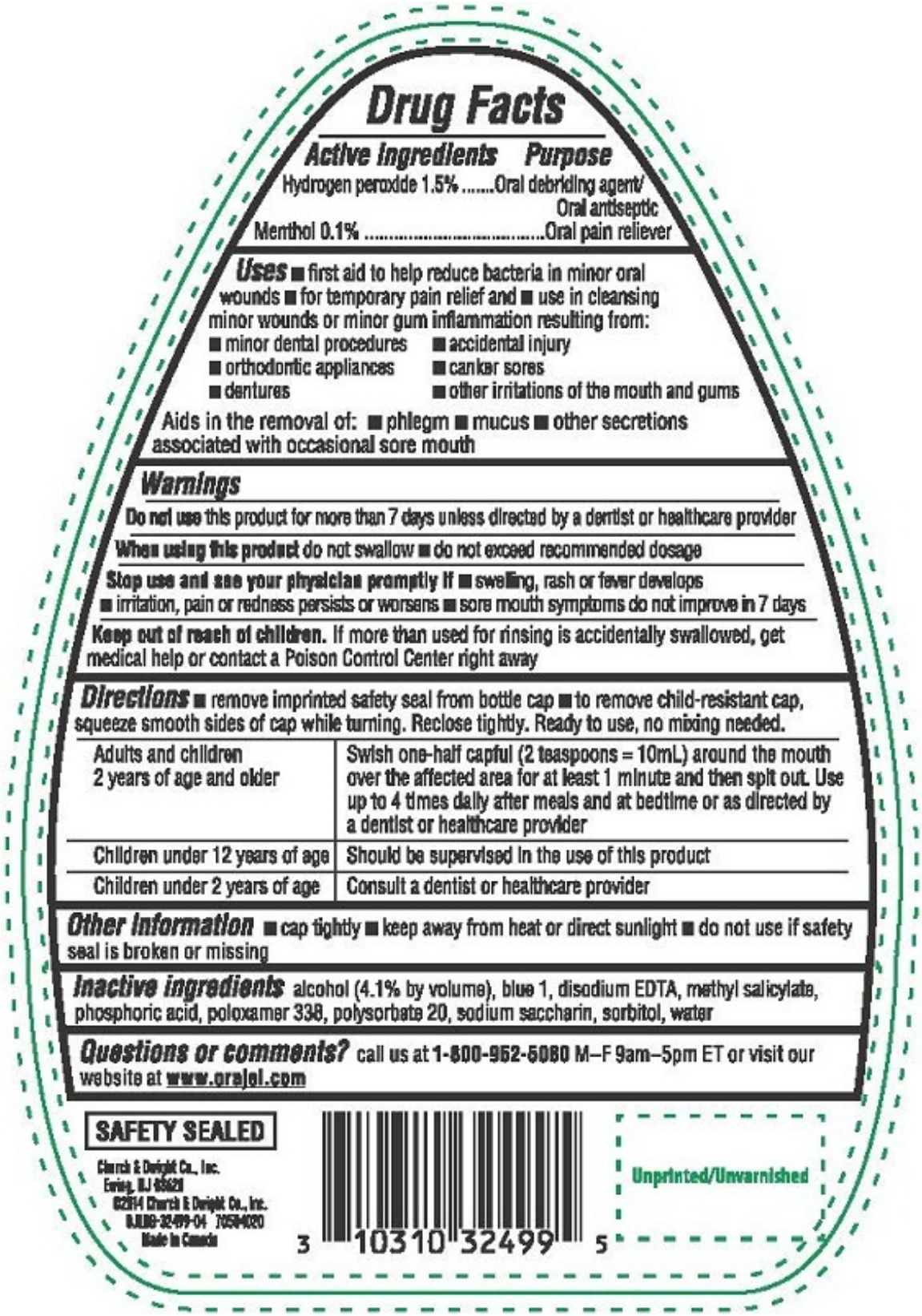
FRESH MINT

ORAL DEBRIDING AGENT / ANTISEPTIC RINSE / PAIN RELIEVER

16 FL OZ (473.2 mL)

Front Label OJLBF-32499-04.jpg

Back Label OJLBB-32499-04.jpg



ORAJEL ANTISEPTIC RINSE FOR ALL MOUTH SORES

hydrogen peroxide 1.5%, menthol 0.1% liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62864-760
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	1.5 mL in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62864-760-16	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(62864-760)

Revised: 10/2014 Church & Dwight Canada Corp.