ORAJEL TOOTHACHE RINSE- benzyl alcohol, zinc chloride liquid
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 Toothache Rinse

Benzyl Alcohol 0.27%

Zinc Chloride 0.15%

Oral pain reliever

Oral astringent

Use for temporary relief of pain due to toothaches, minor irritation of the mouth and gums, occasional minor irritation, pain, sore mouth and sore throat

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 • allergic reaction occurs • sore thoat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting.

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 or over:

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 alcohol (4.1% by volume), blue 1, disodium pyrophosphate, menthol, methyl salicylate, poloxamer 338, polysorbate 20, sodium benzoate, sodium saccharin, sorbitol, tetrasodium pyrophosphate, water

Questions or comments calls us at 800 952 5080 Monday through Friday 9 to 5 ET or visit our website at www orajel com

#1

ORAL PAIN RELIEVER

BRAND FOR TOOTHACHE

NON-NUMBING RELIEF!

Orajel™

For TOOTHACHE

Analgesic & Astringent Rinse

Provides All-Over Oral Pain Relief

Soothes Irritated Gums

Cleans Affected Area

Kills Odor-Causing Bacteria

Soothing

Mint

Rinse

ORAL PAIN RELIEVER/

ASTRINGENT

16 FL OZ (473.2 mL)

ORAJEL TOOTHACHE RINSE

benzyl alcohol, zinc chloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-764
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	2.7 mg in 1 mL

ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CALCIUM DISODIUM PYROPHOSPHATE (UNII: T9L63LWS5A)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-764-16	473.2 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2016	
2	NDC:10237-764-08	236.6 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	12/01/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc		253933600	MANUFACTURE(10237-764)