# ORAJEL 3X MEDICATED FOR TOOTHACHE AND GUM- benzocaine, menthol, zinc chloride gel Church & Dwight Co., Inc.

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## Orajel 3X Medicated For Toothache and Gum, Gel

Benzocaine 20%

Menthol 0.26%

Zinc chloride 0.15%

Oral pain reliever and Oral astringent

#### Use

for the temporary relief of pain due to minor irritation or injury of the mouth and gums

**Methemoglobinemia warning**: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy

**Allergy alert**: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

- more than directed
- for more than 7 days unless directed by a dentist or doctor
- for teething
- in children under 2 years of age

## Stop use and ask a doctor if

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

In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away

#### **Directions**

Adults and children 2 years of	Apply to affected area up to 4 times daily or as directed
age and over	by a dentist or doctor
Children between 2 and 12	Ask a doctor before use. Should be supervised in the
years of age	use of this product
Children under 2 years of age	Do not use

#### Other information

do not use if Tamper-Evident Tab is open before first use ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, water

### **Questions or comments?**

call us at 1-800-952-5080 M-F 9am-5pm ET or visit our website at www.orajel.com

**#1 ORAL PAIN** 

**RELIEF BRAND** 

FOR ADULTS

**EXTRA** 

**STRENGTH** 

Orajel™

3X TOOTHACHE & GUM

**MEDICATED** 

IMMEDIATE PAIN RELIEF

**ORAL PAIN** 

RELIEVER/

**ASTRINGENT** 

Provides

Long-Lasting

Pain Relief\*

Soothes

**Irritated Gums** 

**Delivers Targeted** 

Pain Relief

**GEL** 

**NET WT** 

0.25 OZ (7.0 g)



# **ORAJEL 3X MEDICATED FOR TOOTHACHE AND GUM**

benzocaine, menthol, zinc chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-790
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 mg in 1 g	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g	
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.5 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
METHYL SALICYLATE (UNII: LAV5U5022Y)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)		
PEG-75 LANOLIN (UNII: 091790X7TB)		
SORBIC ACID (UNII: X045WJ989B)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-790- 25	1 in 1 PACKAGE	11/01/2019	
1		2.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10237-790- 42	1 in 1 PACKAGE	11/01/2019	
2		4.2 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:10237-790- 12	1 in 1 PACKAGE	11/01/2019	
3		3.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	11/01/2019	

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

## **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
Church & Dwight Co., Inc.		043690812	manufacture(10237-790)

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