ORAJEL 3X MEDICATED FOR DENTURE PAIN- benzocaine, menthol, zinc chloride gel
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 3X Medicated for Denture Pain - Instant Pain Relief Gel

Benzocaine 20%

Menthol 0.5%

Zinc Chloride 0.15%

Benzocaine - Oral Pain Reliever

Menthol - Oral Pain Reliever

Zinc Chloride - Oral Astringent

Use for the temporary relief of • pain due to minor irritation of the mouth and gums caused by dentures • occasional minor irritation, pain, sore mouth

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 the 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 heartrate • 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

Do not use • 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

Keep out of reach of children. 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 age and over	Apply a thin layer to the affected area. Do not reinsert dental work until irritation/pain is relieved. Rinse out well before reinserting. Apply to affected area up to 4 times daily or as directed by a dentist or doctor
Children between 2 and 12 years of age	Ask a doctor before use. Should be supervised in the use of this product
Children under	

Children under 2 years of age	Do not use

do not use if Tamper-Evident Tab is open before first use

ammonium glycyrrhizate, benzalkonium chloride, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, water

Questions? call us at 800-952-5080 M-F 9am - 5pm or visit **www.orajel.com**

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ORAL PAIN

RELIEVER BRAND

FOR ADULTS

Ready-Open Tube Tip

Orajel™

3X MEDICATED

FOR DENTURE PAIN

INSTANT PAIN RELIEF

GEL

20% Benzocaine to Relieve Pain from Dentures

Astringent to Relieve Gum Irritation

Menthol to Soothe Gums Irritated by Dentures

ORAJEL 3X MEDICATED FOR DENTURE PAIN

benzocaine, menthol, zinc chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-723
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	5 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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-723-25	1 in 1 CARTON	10/05/2018	
1		1 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 NOT FINAL	part356	10/05/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		253933600	MANUFACTURE(10237-723)