ORAJEL MEDICATED FOR TOOTHACHE AND GUM, LIQUID- benzocaine and menthol 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 Medicated for Toothache and Gum, Liquid

Benzocaine 20%

Menthol 0.1%

Oral Pain Reliever

Use for the temporary relief of pain due to • canker sores • minor injury of the mouth and gums • minor irritation of the mouth and gums caused by dentures or orthodontic appliances

Methemoglobinemia warning: Use of this product may cuse methemoglobinemia, a serious condition that must be treated promptly becasue 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 heart rate • shortness or 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

Flammable: keep away from fire or flame. Avoid smoking during application.

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

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 • remove imprinted safety seal from bottle cap

Adults and children 2 years of age and over
- Apply product with cotton swab or finger to the affected area. Use up to 4 times daily or as directed by a dentist or doctor

Children under 12 years of age
- Ask a doctor before use. Should be supervised in the use of this product

Children under 2 years of age
- Do not use

Other Information • do not use if safety seal on bottle cap is broken or missing prior to opening

Inactive Ingredients alcohol (54.5% by volume), flavor, PEG-8, red 40, sodium saccarin, water, yellow 5

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

#1

ORAL PAIN
RELIEVER BRAND
FOR TOOTHACHE
Fast-Acting Liquid!
Orajel
MEDICATED
FOR TOOTHACHE & GUM
Instant Pain Relief
•20% Benzocaine to Relieve Oral Pain
•Menthol to Soothe Gums
CANKER SORES • CHEEK BITES • DENTURE PAIN
IRRITATION FROM BRACES
ORAL PAIN RELIEVER
0.45 FL OZ (13.3mL)

ORAJEL MEDICATED FOR TOOTHACHE AND GUM, LIQUID

benzocaine and menthol liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-796
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 g in 1 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 1 mg

Inactive Ingredients

Ingredient Name	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ALCOHOL (UNII: 3K9958V90M)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-796-45	1 in 1 CARTON	08/07/2020	
1		13.3 mg in 1 BOTTLE, GLASS; 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	08/07/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations

Accupac		071609663	manufacture(10237-796)

Revised: 8/2020

Church & Dwight Co., Inc.