

**ORAJEL MEDICATED FOR TOOTHACHE AND GUM, LIQUID- benzocaine and menthol liquid**  
**Church & Dwight Co., Inc.**

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**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 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 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 saccharin, water, yellow 5

**Questions or comment?** Call us at **800 952 5080** M-F 9am-5pm or visit our website at **[www.oraljel.com](http://www.oraljel.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)

**#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

✓ 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 (13.3 mL)

Church & Dwight Co., Inc.  
Zwing, NJ 08628, USA

The maker of the Orajel™ brand does not  
manufacture store brand oral pain products.  
JUPC-32945-01 72013333



**Drug Facts**

**Active Ingredients**  
Benzocaine 20%  
Menthol 1%  
Oral pain reliever

**Purpose**  
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

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

**Flammability:** 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 itching ■ in children under 2 years of age

**Stop use and ask a doctor 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 safety seal from bottle cap  
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 between 2 and 12 years of age  
Ask a doctor before use. Should be supervised in the use.  
Do not use  
Children under 2 years of age

**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, FD&C red #40, sodium saccharin, water, yellow 5

**Questions or comments?** call us at 1-800-952-5080 M-F 9am-5pm ET or visit our website at [www.orajel.com](http://www.orajel.com)

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## ORAJEL MEDICATED FOR TOOTHACHE AND GUM, LIQUID

benzocaine and menthol liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10237-796
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 mg in 1 mL

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10237-796-45	1 in 1 CARTON	08/07/2020	
1		13.3 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M022	08/07/2020	

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

