

**ORAJEL INSTANT PAIN RELIEF REGULAR- benzocaine 10% 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.*

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**Orajel Regular Mild Toothache Relief**

**Active ingredient**

Benzocaine 20%

**Purpose**

Oral pain reliever

**Use**

- for the temporary relief of pain due to toothaches

**Warnings**

**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 physician or healthcare provider

**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** - cut open tip of tube on score mark

- **Adults and children 2 years of age and over** - Apply a small amount of product to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a physician or healthcare provider

- **Children under 12 years of age** - Should be supervised in the use of this product
- **Children under 2 years of age** - Ask a physicaian or healthcare provider

### Other information

- do not use if tube tip is cut prior to opening
- this preparation is inteded for use in cases of toothache, only as a temporary expedient until a physician can be consulted
- do not use continuously

### Inactive ingredients

ammonium glycyrrhizate, flavor, polyethylene glycol, sodium saccharin, sorbic acid

### Questions or comments?

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

#1 ORAL PAIN

RELIEVER BRAND

FOR TOOTHACHE

Orajel

MEDICATED

FOR TOOTHACHE

INSTANT PAIN RELIEF

Relieves Oral Pain with 10% Benzocaine

NET WT

0.25 oz (7.0 g)



**INSTANT PAIN RELIEF**

✓ Relieves Oral Pain with 10% Benzocaine

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ORAL PAIN RELIEVER

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**Orajel**

SAFETY SEALED  
TUBE TIP

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TUBE TIP

Church & Dwight Co., Inc.  
Ewing, NJ 08629 USA  
ORAJEL is a trademark of  
Church & Dwight Co., Inc.  
The maker of the Orajel™ brand  
does not manufacture store brand  
oral pain products.  
DJFC-22240-07 72013308



CHDW0003  
090328Q1

**Drug Facts**

**Active Ingredient** Benzocaine 10%

**Purpose** Oral pain reliever

**Warnings**

**Use** for the temporary relief of pain due to toothaches

**Warnings:** 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

**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** cut open tip of tube on score mark

Adults and children 2 years of age and over 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 2 years of age Do not use

**Other information** ■ do not use if tube tip is cut prior to opening ■ this preparation is intended for use in cases of toothache, only as temporary expedient until a physician can be consulted

**Inactive ingredients** ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid

**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)

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10237-745
<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	100 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>POLYETHYLENE GLYCOL 1000</b> (UNII: U076Q6Q621)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:10237-745-25	1 in 1 PACKAGE	12/01/2013	
1		2.5 g in 1 TUBE; 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 not final	part356	12/01/2013	

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

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Church Dwight Co., Inc.		043690812	manufacture(10237-745)

Revised: 1/2023

Church Dwight Co., Inc.