

**ORAJEL TOOTHACHE STRIPS- benzocaine, menthol strip**  
**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 Toothache Strips**

Benzocaine 15 mg

Menthol 2.5 mg

Benzocaine - Oral Pain Reliever

Menthol - Oral Pain Reliever

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

**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 to 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 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 physician or healthcare provider • for teething • in children under 12 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 • allergic reaction occurs

Keep out of reach of children. In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away

acid blue 9, glycerin, PEG-8, PEG-90, polycarbophil, potassium sorbate, pullulan, PVP, titanium dioxide, water.

Questions • call us at 800 952 5080 Monday through Friday 9am to 5pm or visit our website at [www.oraljel.com](http://www.oraljel.com)

#1 ORAL PAIN

Reliever Brand

For Toothache

SLOW DISSOLVING STRIPS

For Lasting Relief

Orajel™

TOOTHACHE STRIPS

MEDICATED FOR TOOTHACHE & GUM

INSTANT & TARGETED PAIN RELIEF

• Long-Lasting Pain Relief

•Maximum level of Pain Relief with 15mg Benzocaine\*

- Stays in place for Targeted Relief

- Soothes gums with Menthol

Cool Mint Taste

8 STRIPS

Individually Wrapped

Oral Pain Reliever

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Cool Mint Taste

**8 STRIPS**  
INDIVIDUALLY WRAPPED  
ORAL PAIN RELIEVER



Manufactured for:  
Church & Dwight Co., Inc.  
Ewing, NJ 08520 USA  
Made in the UK, Patent Pending.  
DUTC-9986-02 7201502  
The maker of Orajel™ does not manufacture store  
brand oral pain products.

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**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 ■ for teething ■ in children under 12 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 ■ allergic reaction occurs  
**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** ■ make sure hands are dry and free of moisture as strip may be sticky/tacky ■ tear open pouch and remove blue strip  
**Adults and children** 12 years of age and over  
Using either side of strip, immediately place directly onto the affected area keeping tongue and lips clear. Gently press for 5-10 seconds until strip adheres to the area. Strip will stay in place and dissolve slowly in mouth for up to 1 hour for duration of treatment. Use up to 4 times daily or as directed by a physician or healthcare provider.  
**Other information** ■ do not use if pouch is torn or cut prior to opening ■ do not use continuously ■ for best results, avoid drinking warm beverages or eating for at least one hour after applying the product.  
**Inactive ingredients** acid blue 9, glycerin, PEG-8, PEG-80, polyacrylamide, potassium sorbate, povidone, PVP, titanium dioxide, water.  
**Questions?** Call us at 1-800-952-5000 M-F 9am-5pm ET or visit our website at [www.orajel.com](http://www.orajel.com)

**Drug Facts**  
**Active Ingredients (in each strip)**  
Benzocaine 15 mg  
Menthol 2.5 mg  
Oral pain reliever

**Purpose**  
Oral pain reliever

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



Great for temporary relief  
until you can get to the dentist!

**Orajel™**  
TOOTHACHE STRIPS  
MEDICATED FOR TOOTHACHE & GUM  
INSTANT & TARGETED PAIN RELIEF

**ORAJEL TOOTHACHE STRIPS**

benzocaine, menthol strip

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10237-776
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	150 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	25 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
POLYCARBOPHIL (UNII: W25LM17A4W)	
ACID BLUE 9 AMMONIUM (UNII: 86R7G3C26F)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-776-01	1 in 1 CARTON	01/15/2019	
1		8 g in 1 PACKAGE; 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	11/05/2018	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
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Bio film		734555951	manufacture(10237-776)
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Revised: 1/2020

Church & Dwight Co., Inc.