ORAJEL INSTANT PAIN RELIEF SEVERE- benzocaine 20%, menthol, benzalkonium chloride cream
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 SEVERE Toothache & Gum Relief Plus

TRIPLE MEDICATED

Active ingredient

Benzocaine 20%

Menthol 0.25%

Benzalkonium Chloride 0.1%

Purpose

Oral pain reliever

Oral Pain reliever

Antiseptic

Use

- for the temporary relief of pain due to toothaches
- to help protect against infection in minor oral irritation

Warnings

Allergy alert: do not use this product if you have a histoy 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
- 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 - cut open tip of tube on score mark

- **Adults and children 2 years of age and over -** Apply a samll 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
- Orajel Severe Pain Formula will stay in place for extended duration of relief
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

Inactive ingredients

cellulose gum, gelatin, methyl salicylate, mineral oil, pectin, petrolatum, polyethylene glycol, sodium saccharin

Questions or comments?

call us at **1-800-952-5080** M-F 9am-5pm ET or visit our website at **www.orajel.com**

#1

ORAL PAIN

Reliever for

Toothache

Now with 3X MORE

Active Ingredients vs. Store Brand

ORAJEL™

Instant Pain Relief

SEVERE

Toothache & Gum Relief Plus

Triple Medicated

20% Benzocaine to Relieve Oral Pain

Antiseptic to Help Prevent Infection

Menthol to Soothe

Oral Pain Reliever NET WT 0.33 OZ (9.4g)

Long-Lasting Cream

OJFC-32501-06

#1
ORAL PAIN RELIEVER FOR TOOTHACHE

Now with 3X MORE Active Ingredients vs. Store Brand

Orajel™

Instant Pain Relief

SEVERE

Toothache & Gum Relief Plus

TRIPLE MEDICATED

- ✓ 20% Benzocaine to Relieve Oral Pain
- ✓ Antiseptic to Help Prevent Infection
- ✓ Menthol to Soothe

SAFETY SEALED TUBE TIP

TRIPLE MEDICATED

- ✓ 20% Benzocaine to Relieve Oral Pain
- ✓ Antiseptic to Help Prevent Infection
- ✓ Menthol to Soothe

ORAL PAIN RELIEVER/ANTISEPTIC NET WT 0.33 OZ (9.4 g)

LONG-LASTING CREAM

Orajel
Instant Pain Relief
SEVERE
Toothache & Gum Relief Plus

Church & Dwight Co., Inc.
Ewing, NJ 08628

Made in U.S.A.

OJFC-32501-06 70562151

3 10310 32501 5

NO INK NO VARNISH

090328Q2

NO INK NO VARNISH

Drug Facts

Active ingredients	Purpose
Benzocaine 20%	Oral pain reliever
Menthol 0.25%	Oral pain reliever
Benzalkonium Chloride 0.1%	Antiseptic

Use ■ for the temporary relief of pain due to toothaches ■ to help protect against infection in minor oral irritation

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 ■ 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 ■ 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 physician or healthcare provider

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 a temporary expedient until a physician can be consulted ■ do not use continuously ■ Orajel Severe Pain Formula will stay in place for extended duration of relief ■ avoid using toothpaste or drinking cold drinks or fruit juices for at least one hour after applying

Inactive ingredients cellulose gum, gelatin, methyl salicylate, mineral oil, pectin, petrolatum, polyethylene glycol, sodium saccharin

Questions or comments? call us at 1-800-962-5080 M–F 8am–5pm ET or visit our website at www.orajel.com

ORAJEL INSTANT PAIN RELIEF SEVERE

benzocaine 20%, menthol, benzalkonium chloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-747
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	25 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GELATIN (UNII: 2G86QN327L)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
PECTIN (UNII: 89NA02M4RX)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:10237-747-32	1 in 1 CARTON	02/27/2017	
1		9.4 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	02/27/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church Dwight Co., Inc.		043690812	manufacture(10237-747)