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

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ORAL PAIN

Reliever for

Toothache

Now with 3X MORE

Active Ingredients vs. Store Brand

ORAJELTM

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



TRIPLE MEDICATED

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



SEVERE

TRIPLE MEDICATED

- √ 20[™] Benzocaine to Relieve Oral Pain
- ✓ Antiseptic to Help Prevent Infection
- ✓ Menthol to Soothe

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The makers of Orajel® do not manufacture store brand oral pain products.

Nade in U.S.A.

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Questions or comments? cal us at 1-800-962-5080 M-F Barn-Spr ET or visit our websits at www.enfeld.com

Inactive ingredients cellulose gum, gelatin, methyl sellcylate, mineral cill, peciln, petrolatum, polyethylene

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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	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	200 mg in 1 g	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	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: K679 OBS 311)	
GELATIN (UNII: 2G86QN327L)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
PECTIN (UNII: 89 NA02M4RX)	
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)	

Revised: 4/2017 Church Dwight Co., Inc.