

**ORAJEL DENTURE PAIN RELIEF- benzocaine, benzalkonium chloride, menthol 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.

Orajel Denture Pain

Benzalkonium Chloride 0.1%

Benzocaine 20%

Menthol 0.7%

Benzalkonium Chloride - Oral antiseptic

Benzocaine - Oral pain reliever

Menthol - Oral pain reliever

Use for the temporary relief of • pain due to minor irritation of the mouth and gums caused by dentures • occasional minor irritation, pain, sore mouth.

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

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

Directions

cut open tube on score mark

Adults and children 2 years of age and over:

Apply a thin layer to the affected area. Do not reinsert dental work until irritation/pain is relieved. Rinse out well before reinserting. 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 sue if tube tip is cut prior to opening • this preparation is intended for use in cases of denture pain, only as a temporary expedient until a physician can be consulted • do not use continuously • Orajel Denture Pain Gel will stay in place for extended duration of relief

Inactive Ingredients blue 1, cellulose gum, flavor, gelatin, mineral oil, pectin, petrolatum, polyethylene glycol, sodium saccharin, water

Questions or comments call us at 800 952 5080 Monday through Friday 9-5 or visit our website www.orajel.com

#1

Oral Pain

Reliever Brand

For Adults

New Formula!

3x More

Active Ingredients*

Orajel

Instant Pain Relief

For Denture Pain

Soothes Gum Pain & Irritation

Triple Medicated

10% Benzocaine to Relieve Pain from Dentures

Astringent to Relieve Gum Irritation NEW

Menthol to Soothe Gums Irritated by Dentures

Refreshing Mint

Long-Lasting Gel

Oral Pain Reliever/Astringent NET WT 0.25 OZ (7.0g)

benzocaine, benzalkonium chloride, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-765
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	26 mg in 1 g
BENZOCAINE (UNII: U3RS Y48JW5) (BENZOCAINE - UNII:U3RS Y48JW5)	BENZOCAINE	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
PECTIN (UNII: 89NA02M4RX)	
PETROLATUM (UNII: 4T6H12BN9U)	
GELATIN (UNII: 2G86QN327L)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-765-25	1 in 1 CARTON	07/01/2016	10/18/2019
1		1 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	07/01/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		253933600	manufacture(10237-765)

Revised: 10/2019

Church & Dwight Co., Inc.