ORAJEL 4X MEDICATED FOR TOOTHACHE AND GUM, CREAM- benzalkonium chloride, benzocaine, menthol, zinc 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 4X Medicated For Toothache and Gum, Cream

Active ingredients

Benzalkonium chloride 0.13%

Benzocaine 20%

Menthol 0.26%

Zinc chloride 0.15%

Purpose

Oral antiseptic, Oral pain reliever, Oral astringent

Uses

- for the temporary relief of pain due to minor irritation or injury of the mouth and gums
- first aid to help prevent infection in minor oral irritation

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 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

Adults and children 2 years of age and older

- 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 Tamper-Evident Tab is open before first use
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

Inactive ingredients

ammonium glycyrrhizate, flavor, PEG-8, PEG-75, PEG/PPG 116/66 copolymer, poloxamer 407, sodium saccharin, sorbic acid, titanium dioxide, water

Questions or comments?

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

Principal Display Panel

#1 ORAL PAIN RELIEVER FOR TOOTHACHES

Ready-Open Tube Tip

Orajel

4X MEDICATED FOR TOOTHACHE AND GUM

INSTANT PAIN RELIEF CREAM

Clinical Strength Pain Relief

Proven to Kill Harmful Bacteria

Helps Prevent Infection

Cooling Relief for Gum Irritation

ORAL ANTISEPTIC/PAIN RELIEVER/ASTRINGENT

NET WT

0.33 OZ (9.4 g)

ORAJEL 4X MEDICATED FOR TOOTHACHE AND GUM, CREAM

benzalkonium chloride, benzocaine, menthol, zinc chloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:10237-788
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	2.6 mg in 1 g
ZINC CATION (UNII: 13S1S8SF37) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.5 mg

ZINC CATION (UNII: 1331383F37) (ZINC CATION - UNII:1331383F37)	ZINC CATION	in 1 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
PEG/PPG-116/66 COPOLYMER (UNII: JP0CK963E0)	
SORBIC ACID (UNII: X045WJ989B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-788-33	1 in 1 PACKAGE	11/01/2019	
1		3.3 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	part333A	11/01/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	MANUFACTURE(10237-788)

Revised: 1/2023 Church & Dwight Co., Inc.