

ORAJEL INSTANT PAIN RELIEF MAXIMUM STRENGTH- benzocaine 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.

Drug Facts

Active Ingredients

Benzalkonium chloride 0.02%
Benzocaine 20%
Zinc chloride 0.1%

Purpose

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Oral antiseptic
Oral pain reliever
Oral astringent

Use for the temporary relief of pain associated with canker sores, cold sores, fever blisters, minor irritation or injury of the mouth and gums. 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 is directed
for more than 7 days unless directed by a dentist or doctor

Stop use and ask a doctor if

sore mouth 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 cut open tip of tube on score mark, do not use if tube tip is cut prior to opening

Adults and children 2 years of age and over Apply to affected area up to 4 times daily or as directed by dentist or doctor.

Children under 12 years of age Should be supervised in the use of the product

Children under 2 years of age Ask a dentist or doctor

Inactive ingredients allantoin, carbomer, edetate disodium, mentha piperita (peppermint) oil, polyethylene glycol, polysorbate 60, propylene glycol, propyl gallate, purified water, pvp, sodium

saccharin, sorbic acid, stearyl alcohol

Questions or comments? call us at **1-800-952-5080** M-F 9am-5pm or visit our website at **www.oraljel.com**

Principal Display - carton

*TRIPLE MEDICATED for FAST
EFFECTIVE RELIEF*

Orajel gel

Instant Pain Relief

For all Mouth Sores

MAXIMUM STRENGTH

SAFETY SEALED TUBE TIP

NET WT 0.125 OZ (3.5g)

ASTRINGENT

ORAL PAIN RELIEVER / ORAL ANTISEPTIC / ORAL



carton image

ORAJEL INSTANT PAIN RELIEF MAXIMUM STRENGTH

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-708
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.4 mg in 1 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC - UNII:J41CSQ7QDS)	ZINC CHLORIDE	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
CARBOMER 934 (UNII: Z135WT9208)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0K00R)	
POVIDONE K30 (UNII: U725QWY32X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-708-42	1 in 1 CARTON		
1		11.9 g in 1 TUBE		
2	NDC:10237-708-18	1 in 1 CARTON		
2		5.1 g in 1 TUBE		
3	NDC:10237-708-12	1 in 1 CARTON		
3		3.5 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part356	06/11/2010	

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

Establishment

Name	Address	ID/FEI	Business Operations
Church & Dwight Co., Inc.		043690812	manufacture

Revised: 3/2012

Church & Dwight Co., Inc.