

ORAJEL FOR TOOTHACHE MAXIMUM STRENGTH- benzocaine swab
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 LISTING

Active ingredient	Purpose
Benzocaine 20%	Oral Pain Reliever

Uses for the temporary relief of pain due to toothaches

Warnings

Allergy Alert

do not use this product if your 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 told to do so by a dentist or doctor

Stop use and ask a dentist of doctor if symptoms do not get better 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 awayEnter section text here

Directions

Adults and Children	Hold swab with solid white tip down
2 years of age and older	Bend and snap open swab tip with the colored rings
	Apply product to the cavity and around gum surrounding the teeth
	Use up to 4 times daily or as directed by a dentist or doctor
	Discard swab after application

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

Children under 2 years of age Ask a dentist or doctor

Other information do not use if label seal is broken prior to purchase, or if colored rings on tip are not blue, this preparation is intended for use in cases of toothache, only as temporary expedient until a dentist can be consulted, do not use continuously

Inactive ingredients flavor, polyethylene glycol, purified water, red 40, sodium saccharin, yellow 5

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

Carton image

#1 ORAL PAIN RELIEVER FOR TOOTHACHE

medicated swabs

NEW LOOK!

Orajel

Instant Pain Relief

FOR TOOTHACHE

MAXIMUM STRENGTH

12 UNIT-DOSE SWABS NET 0.06 FL OZ (1.8 ML) EACH

BENZOCAININE 20% ORAL PAIN RELIEVER



Church & Dwight Co., Inc.
Princeton, NJ 08543
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0170-37441-03

FOR TOOTHACHE

Orajel
Instant Pain Relief

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benzocaine swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-705
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-705-12	12 in 1 CARTON		
1		1.8 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/11/2010	

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

Establishment

Name	Address	ID/FEI	Business Operations
SwabPlus, Inc.		876441549	manufacture

Revised: 8/2010

Church & Dwight Co., Inc.