

**ORAJEL SEVERE TOOTHACHE MAXIMUM STRENGTH FAST-ACTING FORMULA-
benzocaine liquid**

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 ingredient

Benzocaine 20%

Purpose

Oral pain reliever

Use for the temporary relief of pain due to toothaches

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.

Flammable: keep away from fire or flame. Avoid smoking during application and until product has dried

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 doctor if

- swelling, rash or fever develops
 - irritation, pain or redness persists or worsens
 - symptoms do not improve in 7 days
-

—

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

- remove imprinted safety seal from bottle cap

adults and
children 2
years and
older

Apply product with cotton swab or finger to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor

Children under
12 years of

Should be supervised in the use of this product

age

Children under 2 years of age Ask a dentist or doctor

Other information

- do not use if imprinted bottle seal is broken or missing prior to opening
- this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted
- do not use continuously

Inactive ingredients alcohol (54.6% by volume), 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**

Principal Display Panel

#1 ORAL PAIN RELIEVER
FOR TOOTHACHE

Orajel liquid
Instant Pain Relief

for **SEVERE TOOTHACHE**

MAXIMUM STRENGTH
FAST-ACTING FORMULA

NET CONTENTS 0.45 FL OZ (13.3 ML) ORAL PAIN RELIEVER BENZOCAINE 20%

Carton image



ORAJEL SEVERE TOOTHACHE MAXIMUM STRENGTH FAST-ACTING FORMULA

benzocaine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-722
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
ALCOHOL (UNII: 3K9958V90M)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10237-722-45	1 in 1 CARTON		
1		13.3 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/21/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, Inc.		071609663	manufacture

Revised: 3/2011

Church & Dwight Co., Inc.