ORAL ANALGESIC MAXIMUM STRENGTH- oral pain reliever gel Meijer Distribution, 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

Uses

Uses temporarily relieves pain associated with:

toothache minor dental procedures

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 told to do so by a dentist or doctor

Stop use and ask a physician if swelling, rash or fever develops; irritation, pain or redness persists or worsens

Keep out of reach of children:

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

Directions

Directions

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

Adults and children 2 years of age and over Apply a small amount of product to the cavity and

around gum surrounding the teeth.

Use up to 4 times daily or as directed by a dentist or

physician

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 This preparation is intended for use in case of toothache, only as a temporary expedient until a dentist can be consulted. Do not use continuously.

Inactive ingredients

Inactive ingredients flavor, polyethylene glycol, sodium saccharin, sorbic acid

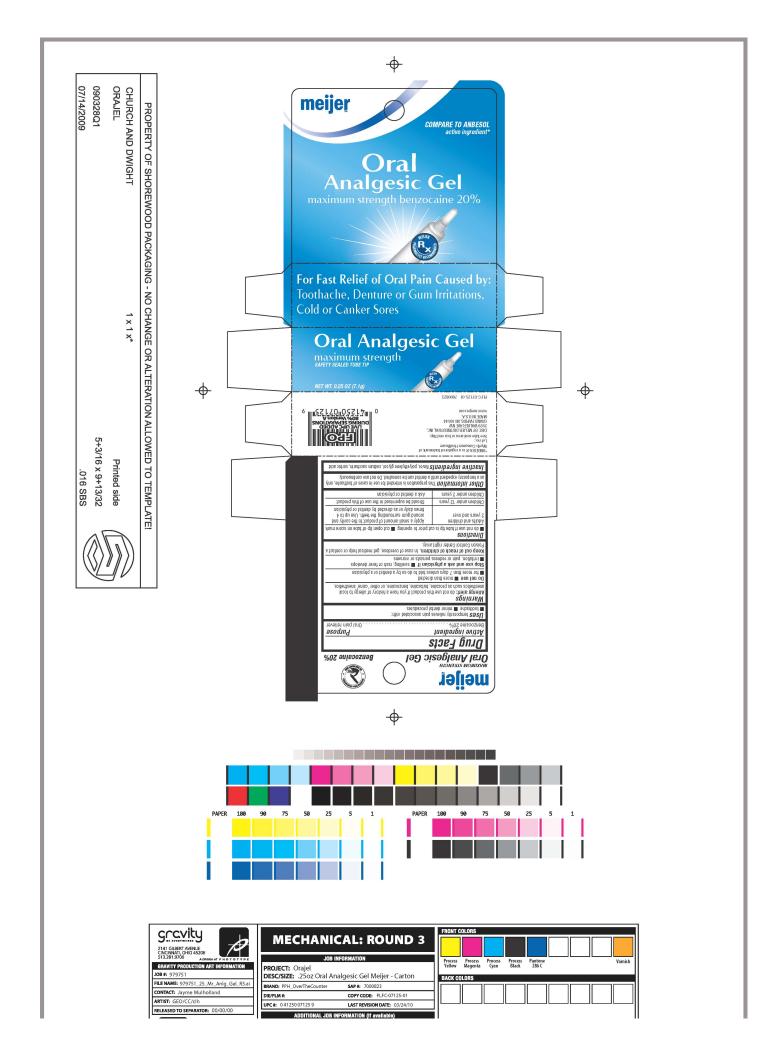
Questions or comments? call us at **1-800-952-5080** M-F 9am-5pm ET or visit our website at **www.orajel.com**

Orajel gel

Instant Pain Relief

for TOOTHACHE
MAXIMUM STRENGTH

NE WT 0.42 OZ (11.9 g) ORAL PAIN RELIEVER BENZOCAINE 20% carton image



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ORAL ANALGESIC MAXIMUM STRENGTH

oral pain reliever gel

Product	Information
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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:41250-701

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Benzocaine (UNII: U3RS Y48 JW5) (Benzocaine - UNII: U3RS Y48 JW5) Benzocaine 200 mg in 1 g

Inactive Ingredients

Ingredient Name Strength
polyethylene glycol (UNII: 3WJQ0SDW1A)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

sorbic acid (UNII: X045WJ989B)

Packaging

1	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-701-25	1 in 1 CARTON		
1		7.1 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/13/2010	

Labeler - Meijer Distribution, Inc. (006959555)

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

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

Revised: 5/2010 Meijer Distribution, Inc.