

**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.*

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**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.

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

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.oraljel.com**

**Orajel      gel**

Instant Pain Relief

for TOOTHACHE  
MAXIMUM STRENGTH

NET WT 0.42 OZ (11.9 g) ORAL PAIN RELIEVER BENZOCAINE 20%

carton image





2141 Gilbert Avenue  
Cincinnati, Ohio 45206  
513.281.0999

**PHOTOTYPE SEPARATION INFORMATION**

SKU JOB #:  
CSR:  
CSR EMAIL:  
DATE:

SEPARATOR: Phototype PRINTER: Shorewood - NJ

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SUBSTRATE:

APP/VERSION: Adobe Illustrator CS3

 Church & Dwight Co., Inc.  
469 North Harrison Street  
Paterson, NJ 086543  
609.683.5900

**C&D APPROVALS**

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Die

**QUALITY ASSURANCE CHECK**

*GRAVITY and PHOTOTYPE have made every effort to ensure that this artwork has been completed accurately. We strongly advise that the client or recipient review this material carefully before signing for its release.*

# ORAL ANALGESIC MAXIMUM STRENGTH

oral pain reliever gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-701
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzocaine</b> (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
polyethylene glycol (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
sorbic acid (UNII: X045WJ989B)	

## Packaging

#	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)

## Establishment

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

