

MEIJER MAXIMUM STRENGTH ORAL PAIN RELIEF- benzocaine, and benzalkonium chloride 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.

Active ingredients	Purpose
Benzocaine 20%.....	Oral pain reliever
Benzalkonium chloride 0.1%.....	Antiseptic

- Use**
- for the temporary relief of pain due to toothaches
 - 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 directed
 - for more than 7 days unless directed by a physician or healthcare provider

- Stop use and ask a physician if**
- swelling, rash or fever develops
 - irritation, pain or redness persists or worsens
 - symptoms do not improve in 7 days
 - allergic reaction occurs

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

Adults and children 2 years of age and over	Apply a small amount of product to the cavity around gum surrounding the teeth.
Children under 12 years of age	Should be supervised in the use of this product
Children under 2 years of age	Ask a physician or healthcare provider

Other information

- do not use if tube tip is cut prior to opening
- this preparation is intended for use in cases of toothache, only as a temporary expedient until a physician can be consulted
- do not use continuously
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

Inactive ingredients glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol

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GRAND RAPIDS, MI 49544

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Made in Korea

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Compare to Orajel® active ingredients*

Maximum Strength

OralPainReliefGel

Benzocaine 20% • Benzalkonium Chloride 0.1%

Double Medicated for Fast Relief

- Benzocaine Works To Relieve Oral Pain
- Benzalkonium Chloride Helps Protect Against Oral Infection

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Maximum Strength

OralPainReliefGel

Benzocaine 20% • Benzalkonium Chloride 0.1%

NET WT 0.42 OZ (11.9 g)

Double Medicated for Fast Relief

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OralPain
ReliefGel
Benzocaine 20%
Benzalkonium Chloride 0.1%



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*This product is not manufactured or distributed by Church & Dwight, Inc., owner of the registered trademark Orajel®.

Lot & Exp.

Drug Facts	
Active ingredients	Benzocaine 20% Benzalkonium chloride 0.1%.....Antiseptic
Use	■ for the temporary relief of pain due to toothaches ■ 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 directed ■ for more than 7 days unless directed by a physician or healthcare provider
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.	■ symptoms do not improve in 7 days ■ allergic reaction occurs
Directions	■ 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.
Children under 12 years of age	Should be supervised in the use of this product
Children under 2 years of age	Ask a physician or healthcare provider
Other information	■ do not use if tube tip is cut prior to opening ■ this preparation is intended for use in cases of toothache, only as a temporary expedient until a physician can be consulted ■ do not use continuously ■ avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying
Inactive ingredients	glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 400, saccharin sodium, sorbitol
Questions or comments?	call 1-800-814-8028

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benzocaine, and benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-782
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-782-42	1 in 1 BOX	12/08/2016	
1		11.9 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/08/2016	

Labeler - MEIJER DISTRIBUTION INC (006959555)

Revised: 12/2016

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