

IODENT MAXIMUM STRENGTH ORAL ANALGESIC - benzocaine gel

United Exchange Corp

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 ingredient

Purpose

Benzocaine 20%.....Oral pain reliever

Uses temporarily relieves pain due to toothache, canker sores, cold sores, fever blisters, minor irritation of the mouth and gums caused by dentures or orthodontic appliances

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 doctor/dentist

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 cap and cut tip of tube on score mark
- adults and children 2 years of age and older: apply a small amount of Oral Analgesic Gel to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a doctor or dentist.
- children under 12 years of age: should be supervised in the use of this product
- children under 2 years of age: ask a doctor/dentist

Other information

- store at 15° to 25°C (59° to 77°F)
- do not use if tube tip is cut prior to opening
- This preparation is intended for use in cases of toothaches, only as a temporary expedient until a dentist can be consulted.
- Do not use continuously
- Lot No. and Exp Date: see box or see crimp of tube

Inactive ingredients flavor mint, glycerin, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol

Distributed by:

United Exchange Corp.

17211 Valley View Ave.

Cerritos, CA 90703 USA

Made in Korea



Compare to the active ingredient of **ORAJEL®**

Provides Immediate Relief From:

- Toothache
- Denture and Gum Irritations
- Cold and Canker Sores

Oral Analgesic Gel

Benzocaine 20%

MAXIMUM STRENGTH

Oral Analgesic Gel

Benzocaine 20%

NET WT 0.42 OZ (11.9 g)

LOT & EXP.



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17211 Valley View Ave.
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Toll Free: 1 800 814 8028
Made in Korea



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

Drug Facts
Active ingredient Benzocaine 20%.....Oral Pain Reliever
Uses For the temporary relief of pain due to toothaches
Warnings 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 doctor if ■ swelling, rash or fever develops ■ irritation, pain or redness persists or worsens ■ symptoms do not get better in 7 days
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benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:65923-010
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (BENZOCAINE)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN	
POLYETHYLENE GLYCOL 400	
POLYETHYLENE GLYCOL 4000	
SACCHARIN SODIUM	
SORBITOL	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-010-11	1 in 1 CARTON		
1		11.9 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/31/2013	

Labeler - United Exchange Corp (840130579)

Revised: 12/2014

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