

IODENT 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.

Iodent Oral Analgesic Gel 0.42 oz 490 (ZDP 2020)

Active ingredient Purpose

Benzocaine 20%.....Oral Pain Reliever

Uses

for the temporary relief of pain due to:

- toothache
- canker sores
- gum pain
- denture pain
- cheek bites

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy Alert: do not use this product if your child has a history of allergy or 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
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness does not go away
- swelling, rash or fever develops

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children:

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 2 years of age and older.	Remove cap and cut tip of tube. 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 doctor.
Children under 12 years of age.	Should be supervised in the use of this product.
Children under 2 years of age.	Do not use.

Other information

- store at room temperature 20° to 25°C (68° to 77°)
- this preparation is intended for use in cases of toothaches, only as a temporary expedient until a dentist or doctor can be consulted
- do not use continuously

Inactive ingredients

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

Distributed by:

United Exchange Corp.

5836 Corporate Ave.

Cypress, CA 90630 USA

1-800-814-8028

Made in China



SAFETY-SEALED TUBE TIP

MAXIMUM STRENGTH

Oral Analgesic Gel

Benzocaine 20% (Oral Pain Reliever)

Fast Relief From:

- Toothache • Canker Sores • Gum Pain • Denture Pain • Cheek Bites

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MAXIMUM STRENGTH

SAFETY-SEALED TUBE TIP

Oral Analgesic Gel

Benzocaine 20% (Oral Pain Reliever)

NET WT 0.42 OZ (11.9 G)



Distributed By:
UNITED EXCHANGE CORP.
 Cypress, CA 90630 USA
 1-888-645-8204
 Made In China
 490-ZDP-BX-R3 | OC-MD-ZDP105-R3



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LOT & EXP.

<p>Drug Facts (continued)</p> <p>Warnings Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:</p> <ul style="list-style-type: none"> ■ pale, gray, or blue colored skin (cyanosis) ■ headache ■ rapid heart rate ■ shortness of breath ■ dizziness or lightheadedness ■ fatigue or lack of energy <p>Allergy Alert: do not use this product if your child has a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.</p> <p>Do not use ■ more than directed ■ for more than 7 days unless directed by a doctor ■ for teething ■ in children under 2 years of age</p> <p>Stop use and ask a doctor if ■ sore mouth symptoms do not improve in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops</p>	
<p>Drug Facts</p> <p>Active ingredient Benzocaine 20%</p> <p>Purpose Oral pain reliever</p> <p>Uses ■ for the temporary relief of pain due to: ■ toothache ■ canker sores ■ gum pain ■ denture pain ■ cheek bites</p>	
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TAMPER EVIDENT: DO NOT USE IF CARTON IS OPEN OR IF TUBE TIP IS CUT PRIOR TO OPENING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.



IODENT ORAL ANALGESIC

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-094
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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-094-11	1 in 1 CARTON	01/02/2018	
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	01/02/2018	

Labeler - United Exchange Corp. (840130579)

Revised: 3/2020

United Exchange Corp.