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.

Iodent Oral Analgesic Gel 0.42oz (490 TG, 2018)

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

IODENT MAXIMUM STRENGTH ORAL ANALGESIC

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:65923-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65923-010-11	1 in 1 CARTON	07/12/2016	
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	05/31/2013	

Labeler - United Exchange Corp (840130579)

Revised: 12/2018 United Exchange Corp