ZAPOTOL DENTIDOL ORAL ANALGESIC- benzocaine, and benzalkonium chloride gel
Productos Zapotol 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 ingredients	**Purpose**
Benzocaine 20%.....	Oral pain reliever
Benzalkonium chloride 0.1%.....	Antiseptic

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.
- 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 doctor/dentist

Stop use and ask a dentist or 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 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

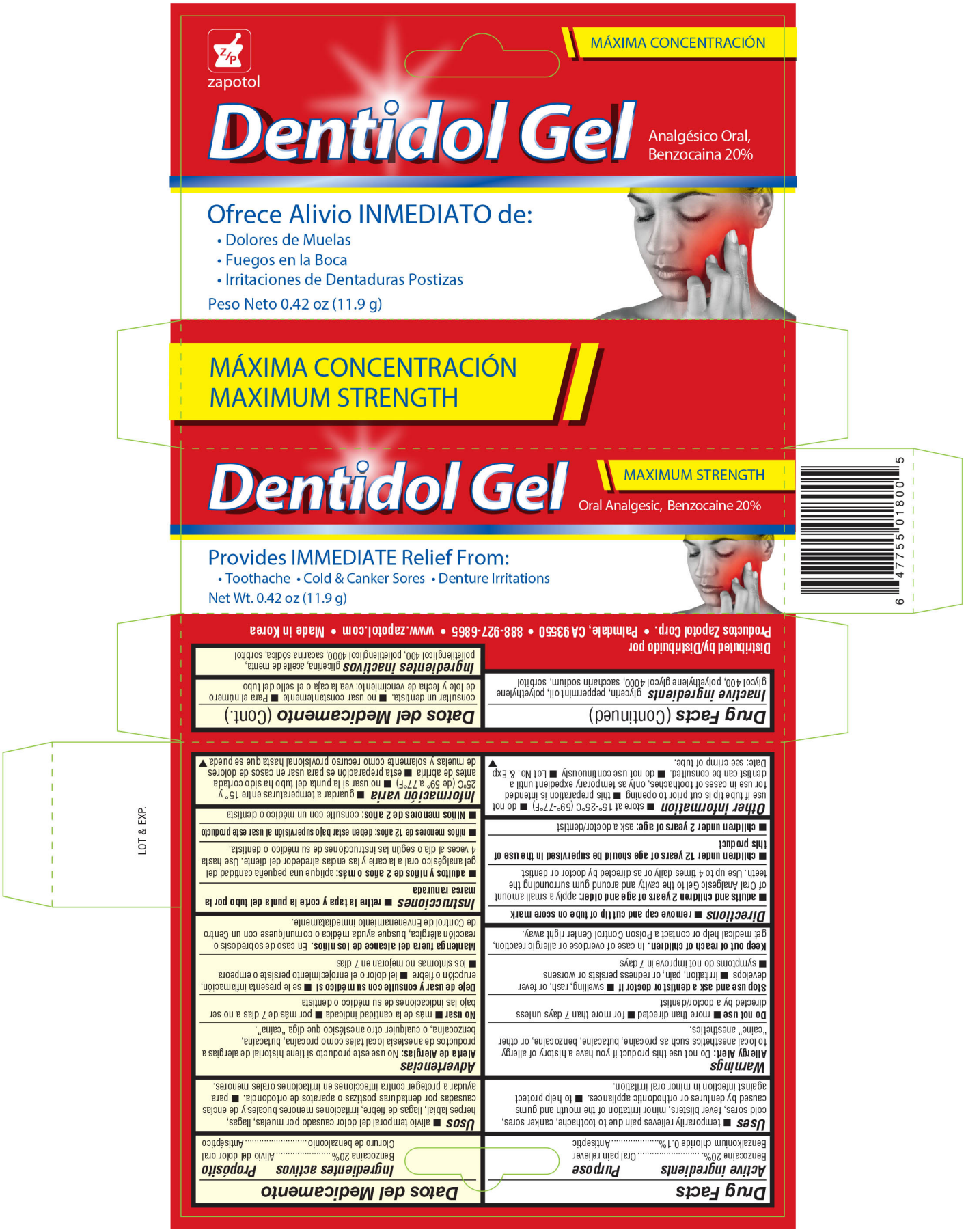
- store at 15°-25°C (59°-77°F)
- do not use if tube tip is cut prior to opening
- this preparation is intended for use in cases of toothaches, only as temporary expedient until a dentist can be consulted.
- do not use continuously
- Lot No. & Exp Date: see crimp of tube.

Inactive ingredients

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

Distributed by:

Productos Zapotol Corp.
Palmdale, CA 93550
Made in Korea



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benzocaine, and benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59428-500
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
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
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:59428-500-42	1 in 1 PACKAGE	11/01/2016	
1		11.9 g in 1 CARTON; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/18/2015	

Labeler - Productos Zapotol Corp. (186063850)

Revised: 11/2016 Productos Zapotol Corp.