

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



zapotol

MÁXIMA CONCENTRACIÓN

Dentidol Gel

Analgésico Oral,
Benzocaina 20%

Ofrece Alivio INMEDIATO de:

- Dolores de Muelas
- Fuegos en la Boca
- Irritaciones de Dentaduras Postizas

Peso Neto 0.42 oz (11.9 g)



MÁXIMA CONCENTRACIÓN
MAXIMUM STRENGTH

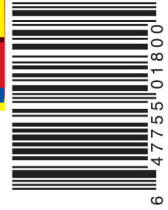
Dentidol Gel

MAXIMUM STRENGTH

Oral Analgesic, Benzocaine 20%

Provides IMMEDIATE Relief From:

- Toothache • Cold & Canker Sores • Denture Irritations
- Net Wt. 0.42 oz (11.9 g)



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Drug Facts (Continued) Inactive ingredients glycerin, peppermint oil, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium, sorbitol	Datos del Medicamento (Cont.) de lote y fecha de vencimiento; vea la caja o el sello del tubo ■ Para el número consultar un dentista. ■ no usar constantemente ■ Para el número de lotes y fechas de vencimiento; vea la caja o el sello del tubo
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Drug Facts Benzalkonium chloride 0.1%.....Antiseptic Benzocaine 20%.....Oral pain reliever Purpose	Datos del Medicamento Cloruro de benzalcónio.....Antiséptico Benzocaina 20%.....Alivio del dolor oral Propósito
Warnings 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.	Advertencias No use este producto si tiene historial de alergias a productos de anestesia local tales como procaína, butacaína, benzocaina, o cualquier otro anestésico que diga "caine". No usar más de la cantidad indicada por más de 7 días a no ser bajo las indicaciones de su médico o dentista. Deje de usar y consulte con su médico si ■ se le presenta inflamación, erupción o fiebre ■ el dolor o el enrojecimiento persiste o empeora ■ los síntomas no mejoran en 7 días Mantenga fuera del alcance de los niños. En caso de sobredosis o reacción alérgica, busque ayuda médica o comuníquese con un Centro de Control de Envenenamiento inmediatamente.
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	Instrucciones retire la tapa y corte la punta del tubo por la marca ramada adultos y niños de 2 años o más: aplique una pequeña cantidad del gel analgésico oral a la cavidad y las encías alrededor del diente. Use hasta 4 veces al día o según las instrucciones de su médico o dentista. niños menores de 12 años: deben estar bajo supervisión al usar este producto
Other information store at 15°-25°C (59°-77°F) ■ do not store at 2°-8°C (36°-46°F) ■ do not use continuously ■ Lot No. & Exp. Date: see crimp of tube. dentist can be consulted. ■ do not use continuously ■ Lot No. & Exp. Date: see crimp of tube. for use in cases of toothaches, only as temporary expedient until a dentist is consulted. ■ this preparation is intended for use in cases of toothaches, only as temporary expedient until a dentist is consulted.	Información varia guarde a temperatura entre 15° y 25°C (de 59° a 77°F) ■ no usar si la punta del tubo o ha sido cortada antes de abrirlo ■ esta preparación es para usar en casos de dolores de muelas y solamente como recurso provisional hasta que se pueda consultar un dentista. ■ no usar constantemente ■ Para el número de lotes y fechas de vencimiento; vea la caja o el sello del tubo

LOT & EXP.

ZAPOTOL DENTIDOL ORAL ANALGESIC
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: 4R4HF16D95)	
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

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